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WRITER'S DIRECT NUMBER

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PATENT & TRADEMARK OFFICE
JC26

December 3, 2003

Express Mail No. EV 166755384US
Mail Stop Petition
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Re: In re: Application of David Howard
USSN: 09/777,472
Response to Petition for Access to An Unpublished Application
Petitioner: ALKAR-RapidPak

Dear Sir:

Enclosed is Applicant David Howard's Objection To Petition For Access To Unpublished Application which is being filed in response the Petition filed by ALKAR-RapidPak on November 7, 2003.

Please note that the application identified in the notice mailed by the Office of Petitions on November 7, 2003 is not correct. The *correct* patent application number to which this Petition refers is David Howard's Patent Application Serial No. 10/369,318, not USSN 09/777,472.

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If you have any questions or if I can be of further service, do not hesitate to contact me.

Sincerely,

FELLERS, SNIDER, BLANKENSHIP,
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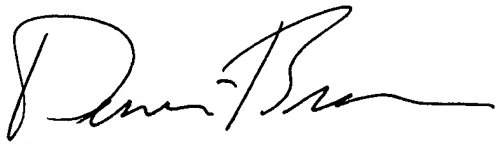

Dennis D. Brown

DDB:caw
Enclosures (236825.1)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): HOWARD Serial No.: 10/369,318 Filed: 02/18/2003 Title: SURFACE PASTEURIZATION OF COOKED FOOD PRODUCTS Attorney Docket No.: 67638/03-066	Group Art Unit: 1761 Examiner: Unknown

MAIL STOP PETITION
COMMISSIONER FOR PATENTS
P. O. BOX 1450
ALEXANDRIA, VA 22313-1450

OBJECTION TO PETITION FOR ACCESS TO UNPUBLISHED APPLICATION

Alkar-RapidPak, Inc., through its patent attorneys at Foley & Lardner, has filed a petition pursuant to 37 C.F.R. 1.14 seeking access to the above-referenced unpublished application of David Howard. However, Alkar has not shown any "special circumstances" which would justify access to Applicant's pending application and, therefore, the petition should be denied.

In the notice mailed by the Office of Petitions on November 14, 2003 (copy attached hereto as Appendix A), the Office indicated that the Petition for Access filed by Alkar appeared to pertain to Mr. Howard's pending patent application Serial No. 09/777,479. However, Applicant submits that the intended application in this matter is not No. 09/777,479 but is actually Mr. Howard's application Serial No. 10/369,318 having claims covering a combined pre and post-packaging pasteurization process discussed hereinbelow.

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Legal Authorities

Applicant is not aware (and apparently, neither is Alkar) of any case of this type where a petition for access has been granted. In *Ex parte Bonnie-B Co.*, 1923 C.D. 42, 313 O.G. 453 (Comm'r Pats. 1922), access was denied even though the applicant had sent the petitioner, a competitor, a notice of infringement based upon the pending application. In *In Re Application for Trimless Cabinets*, 128 USPQ 95 (Comm'r Pats. 1960), the Commissioner, in denying access, stated that:

> The fact that one notifies specific individuals or concerns that there is a pending patent application which may cover the product which that party makes, uses, or sells, is not considered such interference as to warrant waiver of the secrecy guaranteed by the statute and by Rule 14 of the Rules of Practice.

Id. at 95-96. In *In Re Crossman,* 187 USPQ 367 (PTO Solicitor 1975), the Patent Office stated that "'warnings' to the petitioner and its actual or potential customers" that the patent applicant "intended to enforce its patents when and if obtained on the subject applications" amounts to nothing more than "fair notice" and does not exceed the bounds of propriety. *Id.* at 368.

"[T]he circumstances under which disclosure may be made are extremely narrow." *Lee Pharm. v. Kreps*, 577 F.2d 610, 616, 198 USPQ 601 (9th Cir. 1978). "When the customers of the petitioner have not been threatened and the petitioner's business has not suffered, the petition for access will be denied." *Horowitz,* Patent Office Rules and Practice, § 14.9; *In re Trimless Cabinets* 128 USPQ at 96; *In re W.D. Allen Mfg. Co.*, 1961 C.D. 6, 765 O.G. 939 (Comm'r Pats. 1960). As to what might conceivably constitute a sufficient threat to justify granting access, the Commissioner indicated in *Ex parte Bonnie-B Co.* that the patent applicant must have at least demanded that the

petitioner's customers stop marketing or using the device (or process) in question. *Ex parte Bonnie B-Co.*, 313 O.G. at 453.

"Patent applications, pending or abandoned, may contain trade secrets enforceable under state law." D. Chisum, Chisum on Patents, § 11.02[4] (citing *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 181 USPQ 673 (1974); see also, *Larami Corp. v. Lanard Toys Ltd.*, 22 USPQ2d 1440, 1445 fn.3(E.D. Pa. 1992); *Crown Machine Tool Co. v. KVP-Sutherland Paper Co.*, 244 F. Supp 543, 554, 161 USPQ 1, 2-3 (N.D. Cal. 1965).

> Patent applications are preserved in secrecy by both law, 35 U.S.C. § 122, and regulation, 37 C.F.R. § 1.14, for a reason. The integrity of the patent system is maintained in part by inventors' understanding that their patent applications will remain secret until either the patents issue or the applications are otherwise published by the PTO. Breaches of this secrecy undermine the integrity of the patent system.

Eagle Comtronics, Inc. v. Arrow Communication Labs, Inc., 305 F.3d 1303, 1304, 64 USPQ2d 1481 (Fed. Cir. 2002).

Moreover, protecting the statutory confidentiality of a pending patent application and of any trade secrets embodied by or contained in the application is particularly critical when (a) the party seeking disclosure is a competitor, (b) the party seeking disclosure has applied or will apply for its own patents on the same or related subject matter, and/or (c) the party's attorneys are involved in the prosecution of the party's own patent applications. See, e.g., *Ideal Toy Corp. v. Tyco Indus. Inc.*, 478 F. Supp. 1191, 1193, 204 USPQ 17, 19 (D. Del. 1979) (Discovery denied even in litigation context because patent owner would be prejudiced by informing defendant's counsel of developing concepts that defendant could utilize in the prosecution of its own patents); *Eagle Comtronics v. Arrow Communication Labs, Inc.*, 305 F.3d 1303, 1314, 64 USPQ2d 1481 (Fed. Cir. 2002) (Counsel for plaintiff wrongfully used information obtained under protective order from accused infringer's

pending patent application to file two new patent applications for plaintiff); *Microsoft Corp. v. Multi-Tech Sys. Inc.*, 62 USPQ2d 1794 (D. Minn. 2002).

The Inventor - David Howard

The following background information concerning David Howard and his company, Unitherm Food Systems, Inc., is provided to assist the Office of Petitions in understanding the true nature of Mr. Howard's business relationships with Foster Farms, Carolina Turkeys, and Alkar.

Included herewith as Appendix B is the Declaration of David Howard. Mr. Howard is the president of Unitherm Food Systems, Inc. Mr. Howard moved from the UK to the United States in 1992. Prior to moving to the U.S., Mr. Howard invented a unique and valuable process (the "Unitherm browning process") for browning pre-cooked poultry and meat products (e.g., white, bag-cooked whole muscle deli turkey breasts) to produce a naturally roasted appearance. The Unitherm browning process involves applying liquid smoke or MAILLOSE (a liquid smoke-type product produced from sugar) to the pre-cooked product and then quickly heating the product surface in a manner such that very little shrinkage occurs and the product core temperature remains substantially unchanged. The Unitherm browning process has been on-sale and in public use in the U.S. since 1993. (App. B, Howard Declaration, ¶¶ 1-3)

The Unitherm browning process was recently described and claimed in U.S. Patent No. 5,952,027, wrongfully obtained by Prem Singh, an employee of Swift-Eckrich, Inc. (*Id.*, ¶ 4, Exh. 1) In an Order entered August 19, 2002 granting partial summary judgment to Unitherm, Chief Judge Robin J. Cauthron of the U.S. District Court for the Western District of Oklahoma declared the '027 patent invalid in view of the Unitherm process. (*Id.*, ¶ 4, Exh. 2) At trial in March of this

year, the jury found that Swift-Eckrich had obtained the '027 patent by fraud on the Patent Office and awarded damages and attorney fees to Unitherm on a *Walker-Process* antitrust claim. (*Id.*, ¶ 5, Exhs. 3 and 4)

Mr. Howard and Unitherm have also been recognized for breakthrough achievements and discoveries made by Mr. Howard in the field of surface pasteurization. In a study published in the Journal Of Food Protection, Dr. Nanditha Gande and Dr. Peter Muriana confirmed the surprising effectiveness of a continuous infrared pre-packaging process and a combined pre and post-packaging process invented by Mr. Howard, and sold by Unitherm, for surface pasteurizing precooked products. (*Id.*, ¶ 6, Exh. 5, Gande and Muriana *Pre-package Surface Pasteurization Of Ready-To-Eat Meats With A Radiant Heat Oven For Reduction of Listeria Monocytogenes*, Journal Of Food Protection, Vol. 66, No. 9, 2003, pgs. 1623-30.) Mr. Howard's pre-packaging process has shown impressive commercial success and is the subject of another pending patent application, No. 09/777,472, filed by Mr. Howard. Mr. Howard's combined pre and post-packaging process is described and claimed in the above-referenced pending application No. 10/369,318 and is the object of the Petition For Access filed by Alkar.

The importance of Mr. Howard's discoveries and achievements were recently recognized in Compliance Guidelines issued by the USDA Food Safety Inspection Service (FSIS) to control *listeria monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products. The requirements of the agency's final rule provided only three alternative lethality treatments which processing plants can use in their mandatory *listeria* control programs. One of these procedures is the Unitherm pre/post-packaging process invented by Mr. Howard. The guidelines also cite and

adopt the Gande and Muriana study. (*Id.*, ¶ 7, Exh. 6, pgs. 1-4, 10, and 11) Moreover, the Unitherm infrared process is the only pre-packaging process endorsed in the FSIS guidelines.

As already mentioned, Alkar's petition seeks access to Mr. Howard's pending application No. 10/369,318, having claims covering a combined pre and post-packaging surface pasteurization process. As discussed in the pending application, the pre-packaging and post-packaging steps of the combined method will preferably not cause any substantial shrinkage and will not significantly increase the core temperature of the product. The pre-packaging step of the combined procedure will most preferably be conducted using Unitherm's continuous infrared surface pasteurization system. However, the pre-packaging step can alternatively be accomplished using an appropriately modified version of the Unitherm browning process.

In addition to being more effective than the post-packaging pasteurization processes attempted heretofore, Mr. Howard's combined pre/post-packaging process provides significant cost savings. Mr. Howard's pre/post process can, for example, reduce or eliminate the need for supplemental chemical treatments. More importantly, Mr. Howard's inventive pre/post process can effectively accelerate the post-packaging step to such a degree that a standard product bag can be used. In contrast, prior post-packaging pasteurization procedures have required the use of a high abuse product bag which costs about 20 cents more than the standard product bag. (*Id.*, ¶ 8)

All of Mr. Howard's pending patent applications contain valuable proprietary and/or trade secret information which goes beyond the information contained in the Gande and Muriana study and which is not known by Unitherm's competitors. Unitherm intends to keep all such information confidential to the fullest extent possible, unless and until patents are granted therefor.

Foster Farms

Petitioner Alkar asserts that Mr. Howard's communications with Foster Farms were "unsolicited" and implies that Foster Farms is a customer of Alkar, not of Unitherm. Alkar's portrayal of Unitherm's relationship with Foster Farms is misleading and disingenuous, to say the least.

Foster Farms purchased an in-line browning system from Unitherm in 1997 (*Id.*, ¶ 9, Exhs. 7A-7D) The system includes a Unitherm RapidFlow circulating air oven and is used by Foster Farms to brown pre-cooked deli turkey breasts in accordance with the Unitherm browning process.

In August, 2001, Foster Farms sent Unitherm a purchase order agreement for a post-packaging pasteurizer system. (*Id.*, ¶ 10, Exh. 8) The system was to be used to pasteurize packaged product that had been browned in the Unitherm browning system. (*Id.*, pg. 4.) However, as reflected by the fact that special high temperature abuse bags would be required in the post-packaging process with a water residence time of 90-150 seconds, it was not contemplated that the Unitherm browning system would be modified to provide a pre-packaging surface pasteurization step which would be used in combination with the post-packaging system. (*Id.*)

Unitherm signed the Foster Farms purchase agreement on September 25, 2001 (*Id.*, pg. 15) and issued a sales order. (*Id,* Exh. 9) Foster Farms then canceled the order. (*Id.*, ¶ 12, Exh. 10) Until about March 2002, Unitherm was not aware that Alkar or anyone else was bidding against Unitherm for the sale of the post-packaging pasteurizer. Rather, Foster Farms told Mr. Howard that it had been forced to cancel its order with Unitherm because Foster Farms had fallen on hard times. (*Id.*) Unitherm had even been assisting Foster Farms in working with Oklahoma State University to establish appropriate post-packaging protocols for the Foster Farms plant. (*Id.*)

In this same context, at the end of 2001 or the beginning of 2002, Mr. Howard told Tim McConnell of Foster Farms that he had developed an effective combination pre/post-packaging pasteurization process which would preferably be performed using a Unitherm infrared system but could alternatively be accomplished with appropriate modification of the Unitherm browning process. (*Id.*, ¶ 13) Unitherm faxed a letter to Tim McConnell of Foster Farms on May 12, 2003 offering to license this patent pending pre/post-combination process for one cent per pound. (Petitioner's Exh. A) The benefit to Foster Farms is obvious. By simply allowing Foster Farms to use a standard product bag rather than a high abuse bag, the inventive process could reduce Foster Farms' overall cost for producing nine pound deli turkey breasts by eleven cents each. At the time Unitherm sent this letter, certain claims had been allowed in Mr. Howard's pending patent application No. 09/777,472 for the infrared pre-packaging process.

Mr. Howard's letter to Mr. McConnell speaks for itself. The letter is very cordial. Mr. Howard does not claim to have obtained any patent rights in the pre/post-pasteurization process, or in any other process. Nor does Mr. Howard demand that Foster Farms stop using any current process. Nor does Mr. Howard demand that Foster Farms not adopt any new processes. Mr. Howard does not even suggest any potential dispute or litigation in the future. Moreover, Unitherm had no belief that Foster Farms was using any pre/post process or that Foster Farms had any intention of using any pre/post process in the future. (App. B, Howard Declaration, ¶ 14)

Contrary to other bogus assertions made by Alkar, the letter to Mr. McConnell does not state or even suggest that the license offered by Unitherm would require the purchase of any Unitherm equipment. Rather, Unitherm simply offered to license its technology for a royalty amounting to less than the packaging savings alone. Alkar and Foster Farms both plainly know that the Unitherm

license offer did not require that any equipment be purchased from Unitherm or that Foster Farms would be required to stop using whatever equipment it purchased from Alkar. (*Id.*)

Also contrary to Alkar's allegations, Mr. Howard's letter neither mentions Alkar nor disparages any of Alkar's products. In fact, the letter has nothing to do with Alkar or any post-packaging pasteurizer which Alkar may have sold Foster Farms. Alkar also admits on page 6 of its brief that the Alkar pasteurizer does not and cannot perform all of the process steps discussed in Mr. Howard's letter. Nor does Alkar indicate that it has ever attempted to sell or that it urged or attempted to induce Foster Farms to somehow assemble or use such a process.

Foster Farms' response to Mr. Howard on June 12, 2003 also belies Alkar's allegations. (Petitioner's Exh. C.) This letter was also very cordial. There was no or hint or suggestion whatsoever that Foster Farms was concerned about any process it was presently using or may have intended to use in the future. The letter provided no indication that Foster Farms perceived any kind of threat from Unitherm. Rather, Foster Farms indicated that it would be interested in discussing the new Unitherm technology and the letter shows that Foster Farms understands technology licensing. Foster Farms boasted that it was actively involved in licensing its own technology.

Finally, Alkar states that Unitherm has not provided any further information to Foster Farms regarding its "asserted patent rights." However, aside from the fact that Unitherm has never asserted any patent rights in this process, the petitioner also failed to mention the very threatening letters which the petitioner sent to Unitherm. (App. B, Howard Declaration, Exhs. 15 and 16) Nor did the petitioner provide copies of its letters, or of Unitherm's responses thereto. (*Id.*, Exhs. 17 and 18) The petitioner's efforts to intimidate Unitherm and force Unitherm to disclose its proprietary trade secrets and know-how are discussed hereinbelow.

Carolina Turkeys

In contrast to its discussion of Foster Farms, Alkar does not even attempt to suggest that the information which Unitherm provided to Carolina Turkeys was unsolicited. Pursuant to discussions in November 2002 between Mr. Howard and Jay Jandrain of Carolina Turkeys, Mr. Howard faxed Mr. Jandrain a quote for a Unitherm combination pre/post-pasteurization system on December 9, 2002. (*Id.*, ¶ 15, Exh. 11) The assembly employed a Unitherm continuous infrared system in the pre-packaging pasteurization step. Mr. Howard also informed Mr. Jandrain that he could obtain data confirming this process from Dr. Peter Muriana at Oklahoma State University. The system quoted on December 9, 2002 was sized for processing 55 pieces per minute. Mr. Howard sent Mr. Jandrain a second letter on December 20, 2002 pricing an otherwise identical system sized for processing 65 pieces per minute. (*Id.*, ¶ 16, Exh. 12)

As indicated in Alkar's Exhibit G, Dan Blackshear and other employees of Carolina Turkeys saw Unitherm's infrared pre-packaging and pre/post-packaging surface pasteurization processes on display at the Atlanta Poultry Show in January 2003. At that time, Mr. Howard also mentioned that patent applications were pending on these processes. (App. B, Howard Declaration, ¶ 17)

Subsequent to the trade show, Mike Bliss of Carolina Turkeys informed Mr. Howard that Carolina Turkeys had decided not to pursue the Unitherm pre/post system. However, it was Mr. Howard's understanding, based upon this conversation, that Carolina Turkeys had decided to duplicate Mr. Howard's pre/post process using a Unitherm-type browning system in the pre-packaging pasteurization step. (*Id.*, ¶ 18) Mr. Howard sent letters to Mr. Jandrain, Mr. Blackshear, and Mr. Bliss noting that the claims then pending in Mr. Howard's application would read on a pre/post-pasteurization method of this type and offering to license this technology for one cent per

pound. Mr. Howard did not indicate that any patent rights had yet been obtained and did not demand that Carolina Turkeys stop using any process or not adopt any new processes in the future. Rather, Mr. Howard simply indicated that he wished to avoid any conflict at a later date. In all other aspects, the letter sent to Carolina Turkeys did not differ in any significant way from Mr. Howard's letter to Foster Farms. (*Id.* and Petitioner's Exhs. D, F, and G.)

In any event, Unitherm's discussions and correspondence with Carolina Turkeys are completely moot and are irrelevant to Alkar's petition for access. After receiving the letter which Mr. Howard sent on June 11, 2003, Mr. Bliss informed Mr. Howard that Mr. Howard's understanding of Carolina Turkey's future intentions was incorrect and that Carolina Turkeys was not planning to implement a pre/post-pasteurization process comprising the steps outlined in Mr. Howard's letters. (App. B, Howard Declaration, ¶ 18) Moreover, in Alkar's Exh. F, Mr. Bliss confirms in his own handwriting that Mr. Howard's previous understanding of Carolina Turkeys' intentions was incorrect and that Carolina Turkeys has no plans to use a "browning oven" as a pre-pasteurizer. (Petitioner's Exh. F.)

The Petitioner-Alkar-RapidPak, Inc.

Alkar is a competitor of Unitherm. In April of this year, Alkar's president contacted David Howard and indicated that Alkar was interested in purchasing Unitherm. (App. B, Howard Declaration, ¶ 19, Exh. 13) In the course of these discussions, Alkar informed Mr. Howard that Alkar had filed its own patent application(s) for surface pasteurization and had been actively seeking to license this technology. (*Id.*, ¶ 19, Exhs.13 and 14) It is Unitherm's belief that the Alkar attorneys who filed this petition are also responsible for prosecuting Alkar's pending patent application(s) for

surface pasteurization. Of course, because Alkar and Unitherm are competitors in this field, any potential customers contacted by Alkar concerning its patent pending technology would also be existing and/or potential customers of Unitherm.

On July 1 and July 30, 2003, Alkar sent letters to Mr. Howard accusing Mr. Howard and Unitherm of asserting patent rights to prospective and current customers of Alkar and also accusing Unitherm of attempting to coerce Alkar's customers to purchase equipment from Unitherm instead of purchasing equipment from Alkar. (*Id.*, Exhs. 15 and 16) As shown above, these accusations are plainly false.

Unitherm responded to Alkar's allegations in letters mailed July 18, 2003 and August 11, 2003. (*Id.*, Exhs. 17 and 18) In the August 11, 2003 letter, Unitherm summarized the essential points in this matter as follows:

- Unitherm has not yet obtained any issued patents for its surface pasteurization technology.
- Unitherm has never claimed to have yet obtained any patents for its surface pasteurization technology.
- Unitherm is not aware of anyone in the industry that has used or is presently using a combined pre and post-pasteurization process of the type called for in Unitherm's pending patent applications.
- Unitherm has never threatened to take any legal action against anyone for any reason concerning Unitherm's proprietary surface pasteurization technology.
- Unitherm has never "coerced" any customer of Alkar.
- Unitherm has not disparaged Alkar or its products.
- Unitherm is under no obligation to disclose, and will not be bullied or coerced into disclosing, its proprietary surface pasteurization technology and information to its competitors.

Unitherm also noted that:

> We are also puzzled by your apparent contention that it is somehow improper for Unitherm to offer licenses for proprietary technologies which have not yet been patented. Such contention would clearly not be correct and would also conflict with Alkar's own recent attempts to generate interest in the licensing of its purported proprietary technology for pasteurizing wieners.

Alkar has not presented any affidavits or documents refuting any of the points made in Unitherm's letters of July 18 and August 11, 2003. Nor has Alkar presented any affidavits or documents establishing that Unitherm has ever demanded that anyone either stop using any current processes or not adopt any new processes in the future. In addition, Alkar has not presented any affidavits or documents supporting its bald assertions that it has suffered any actual damage. Rather, Alkar's own documents prove that (a) Alkar made sales to Foster Farms and Carolina Turkeys, (b) no sales were lost, and (c) none of the terms or conditions of Alkar's original sales agreements have changed.

Alkar simply wishes to fish through Mr. Howard's patent applications and learn Unitherm's trade secrets and proprietary information. The only "threat" for which Alkar is concerned is the "threat" of competition, particularly from a much smaller, innovative company like Unitherm.

Conclusion

In view of the above, Applicant respectfully submits that Alkar's petition for access to the pending patent application of David Howard should be denied.

Respectfully submitted,

Dennis Brown 12/3/03

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321 SOUTH BOSTON SUITE 800
TULSA OK 74103-3318

(Applicants)

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OFFICE OF PETITIONS

In re Application of
David Howard
Application No. 09/777,472
Filed: February 6, 2001
For: PASTEURIZATION OF FOOD PRODUCTS

: Three
: Week
: Letter

A petition for access was filed by Rick L. Abegglen attorney for ALKAR-RapidPak for access to certain application(s) on November 7, 2003 concurrently with a protest under 37 C.F.R. 1.291.

The petition was filed with proof of service upon applicant. Accordingly, a copy of the petition is not included herewith.

A review of Office records indicates that the above-identified application is the intended application. If this determination is incorrect, Applicant should indicate which application(s) are the correct application(s).

The petition refers to 37 C.F.R. 1.14(j), which was modified on June 30, 2003, to become paragraph 1.14(h) effective July 30, 2003. See 68 FedReg. 38611 at 38625.

A member of the public may be entitled to access if "special circumstances" are shown which warrant a grant of access under 35 U.S.C. § 122. See Manual of Patent Examining Procedure (MPEP), Section 103. Assuming, arguendo, that David Howard has filed such an application, the use of such application to interfere with the business of others may be such special circumstances. Ex parte Bonnie-B Co. Inc., 1923 C.D. 42; In re Application for Trimless Cabinets, 128 USPQ 95 (Comm'r Pats. 1960); and In re Crossman, Kenrick, and LeMieux, 187 USPQ 367 (PTO Sol. 1975).

Petitioner urges that access should be granted to the above-identified application because of alleged interference in their business which they believe constitutes special circumstances. The interference described in the petition is a series of letters from David Howard of Unitherm Food Systems, Inc., Carolina Turkeys and Alkar inviting the licensing of Unitherm's technology and identifying certain activities that allegedly infringe rights to be conveyed by the above-identified

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application.

Applicants are hereby given THREE WEEKS from the date of this letter to file an opposition to this access request. If applicants reply within the three week period, applicants' comments will be considered in deciding the petition. See MPEP section 103.

Correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA. 22313-1450

By fax: (703) 872-9005
Attn: Access Reply Letter

By hand: Office of Petitions
2201 South Clark Place
Crystal Plaza Four, Suite 3C23
Arlington, VA 22202

Telephone inquiries should be directed to Michael L. Lewis at (703) 306-5585.

For Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

APPENDIX B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): HOWARD Serial No.: 10/369,318 Filed: 02/18/2003 Title: SURFACE PASTEURIZATION OF COOKED FOOD PRODUCTS Attorney Docket No.: 67638/03-066	Group Art Unit: 1761 Examiner: Unknown

DECLARATION OF DAVID HOWARD

I, David Howard, declare that the following statements are based upon my personal knowledge and that they are true to the best of my knowledge and belief.

1. I moved from the United Kingdom to the United States in 1992. I presently reside in Tulsa, Oklahoma.

2. I am the president of and the custodian of documents and records for Unitherm Food Systems, Inc.

3. Prior to moving to the U.S., I conceived and successfully performed a process (the "Unitherm browning process") for browning pre-cooked hams and other pre-cooked whole muscle meat and poultry products without substantially shrinking and without substantial increasing the internal core temperatures of the products. The Unitherm browning process has been on-sale and in public use in the U.S. since 1993 and involves applying liquid smoke or MAILLOSE (a liquid smoke-type product produced from sugar) to the pre-cooked product followed by heating the product in Unitherm's RapidFlow continuous circulating air oven.

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4. The Unitherm browning process is described and claimed in U.S. Patent No. 5,952,027 (Exhibit 1 to this Declaration), issued to Prem Singh of Swift-Eckrich, Inc. Exhibit 2 is an Order of partial summary judgment for Unitherm entered August 19, 2002 declaring the '027 patent invalid in view of the Unitherm process.

5. Exhibits 3 and 4 are Judgments awarding damages and attorney fees to Unitherm against Swift-Eckrich on a *Walker-Process* antitrust claim. These judgments were entered following a trial in March 2003 wherein the jury also found that Swift-Eckrich obtained the '027 patent by fraud on the Patent Office.

6. Exhibit 5 is a copy of Gande and Muriana, Pre-Packaged Surface Pasteurization Of Ready-To-Eat Meats With A Radiant Heat Oven For Reduction Of *Listeria Monocytogenes*, Journal of Food Protection, Vol. 66, No. 9, 2003, pgs. 1623-30. The article describes and provides the results of a study conducted at Oklahoma State University of (a) a continuous infrared pre-packaging surface pasteurization process and system which I invented and which is described and claimed in my presently pending U.S. Patent Application No. 09/777,472 and (b) a combined pre and post-packaging surface pasteurization process which I invented and which is described and claimed in my above-referenced pending U.S. Patent Application No. 10/369,318 and which is the object of the Petition For Access filed by Alkar-RapidPak, Inc.

7. Exhibit 6 is a copy of the recently issued USDA-Food Safety Inspection Service (FSIS) Compliance Guidelines to Control *Listeria Monocytogenes* In Post-Lethality Ready-To-Eat Meat and Poultry Products. The agency's final rule cites the Unitherm pre/post-packaging process which I invented as one of only three alternative lethality treatments which processing

plants can use in their mandatory *Listeria* control programs. The agency guidelines also cite and adopt the Gande and Muriana study.

8. In addition to the effectiveness of my pre/post-packaging process as confirmed in the Gande and Muriana study, the pre/post process can provide significant cost savings by (a) reducing or eliminating supplemental chemical treatments and (b) accelerating the post-packaging pasteurization step to such a degree that a standard product bag rather than a costly high abuse bag can be used. The cost differential benefit realized by the use of standard product bags rather than high abuse bags is presently approximately 20¢ per bag.

9. Exhibits 7A- 7D are a Foster Farms purchase order, a sales order, a Unitherm invoice, and the first of three Foster Farms payments showing Unitherm's sale of a Unitherm in-line browning system to Foster Farms in 1997 for browning pre-cooked, nine pound, deli turkey breasts using the Unitherm browning process.

10. Exhibit 8 is a Purchase Order from Foster Farms to Unitherm dated August 28, 2001 for a Unitherm post-packaging pasteurizer system. As reflected on page 4, the system was to be used to pasteurize packaged product which has been browned in the Unitherm browning system which Foster Farms had previously purchased. As reflected by the fact that special high temperature abuse bags were to be used and that the water residence time in the post-packaging process was to be 90-150 seconds, no modification of the Unitherm browning system was contemplated which would provide an effective pre-packaging surface pasteurization step to be used in combination with the post-packaging system. Unitherm signed the Purchase Order agreement on September 25, 2001.

11. Exhibit 9 is a Sales Order issued by Unitherm on September 25, 2001 for the sale of the Unitherm post-packaging pasteurizer system to Foster Farms.

12. Foster Farms then cancelled its order for the Unitherm post-pasteurizer on about October 1, 2001. Exhibit 10 is an October 1, 2001 Fax Transmittal from me to Phil Green and Shawn Pliska of Foster Farms acknowledging Foster Farms' cancellation of the order. Until about March 2002, I was not aware that anyone was bidding against Unitherm for the sale of the post-pasteurizer. Rather, as reflected in the October 1 Fax Transmittal, I was told by Foster Farms that Foster Farms had fallen on hard times and was thus forced to cancel the order. Unitherm had also been assisting Foster Farms in working with Oklahoma State University to establish appropriate post-packaging protocols for the Foster Farms processing facility.

13. At the end of 2001 or the beginning of 2002, I told Tim McConnell of Foster Farms that I had developed an effective combination pre/post-packaging pasteurization process which would preferably be performed using the Unitherm infrared system but could alternatively be accomplished with appropriate modification of the Unitherm browning process.

14. Exhibit A to Alkar's petition is a letter which I faxed to Mr. McConnell on May 12, 2003 offering to license my patent pending pre/post-combination process technology for 1¢ per pound. At no time have I claimed to have yet obtained any patent rights in my surface pasteurization processes. Nor have I demanded that anyone stop using any current pasteurization process or that anyone not adopt any new processes. Nor have I threatened anyone with any litigation, either in the present or in the future. Nor have I demanded that any licensee of the Unitherm process must purchase any Unitherm equipment or must not purchase or must stop using any equipment supplied by others. Also, at the time of my letter to Mr. McConnell, I had

no belief that Foster Farms was using any combined pre/post-packaging pasteurization process or had any intention of using any pre/post process in the future.

15. Exhibit 11 is a quote which I e-mailed on December 9, 2002 to Jay Jandrain of Carolina Turkeys for a Unitherm combination pre/post-pasteurization system. The quote was sent pursuant to discussions which I had with Mr. Jandrain in November 2002.

16. Exhibit 12 is a quote which I e-mailed to Mr. Jandrain on December 20, 2002 for a larger pre/post-pasteurization system.

17. As indicated in Exhibit G to the petitioner's brief, Dan Blackshear and other employees of Carolina Turkeys saw Unitherm's infrared pre-packaging and combined pre/post-packaging surface pasteurization processes on display in January 2003 at the Atlanta Poultry Show. At that time, I informed them that patent applications were pending on these processes.

18. After the Atlanta show, I was informed by Mike Bliss of Carolina Turkeys that Carolina Turkeys had decided not to pursue Unitherm's pre/post system. However, it was my understanding based on this conversation that Carolina Turkeys intended to duplicate the Unitherm pre/post process using a Unitherm-type browning system in the pre-packaging pasteurization step. I noted this in letters (Petitioner's Exhibits D, F, and G) which I subsequently sent Carolina Turkeys and also noted that it was my objective to avoid any conflict at a later date. In response, I was informed by Mr. Bliss that my understanding was incorrect and that Carolina Turkeys was not planning to implement a pre/post-pasteurization process comprising the steps indicated in my letters.

19. In April 2003, Alkar's president contacted me and indicated that Alkar was interested in purchasing Unitherm. Exhibit 13 is a confidentiality agreement which Alkar's

president signed in order to receive Unitherm financial information. In the course of these discussions, Alkar's president informed me that Alkar had filed its own patent applications for surface pasteurization and was actively seeking to license this patent pending technology. Exhibit 14 is an Alkar advertisement which I received wherein Alkar claims patent pending status for its "RapidPak Flash Pasteurization" technology.

20. Exhibits 15 and 16 are letters dated July 1 and July 30, 2003 which I received from petitioner Alkar's attorney.

21. Exhibits 17 and 18 are responses which Unitherm sent to petitioner Alkar on July 18 and August 11, 2003

I declare that all statements made herein of my own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001.

DAVID HOWARD

Date: 3 December 2003

236564.1

US005952027A

United States Patent [19]

Singh

[11] Patent Number: 5,952,027

[45] Date of Patent: Sep. 14, 1999

[54] METHOD FOR BROWNING PRECOOKED, WHOLE MUSCLE MEAT PRODUCTS

[75] Inventor: Prem S. Singh, Glen Ellyn, Ill.

[73] Assignee: Swift-Eckrich, Inc., Downers Grove, Ill.

[21] Appl. No.: 09/075,608

[22] Filed: May 11, 1998

[51] Int. Cl.[6] A23L 1/025; A23B 4/044

[52] U.S. Cl. 426/305; 426/103; 426/237; 426/241; 426/250; 426/262; 426/268; 426/270; 426/293; 426/302; 426/315; 426/641; 426/643; 426/644; 426/645; 426/647; 426/652

[58] Field of Search 426/92, 103, 237, 426/241, 242, 248, 250, 262, 268, 270, 293, 302, 305, 315, 641, 643, 644, 645, 647, 652, 240

[56] References Cited

U.S. PATENT DOCUMENTS

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1,502,905	7/1924	Colgin	426/262 X
3,106,473	10/1963	Hollenbeck	99/229
4,372,981	2/1983	Lieberman	426/315 X
4,657,765	4/1987	Nicholson et al.	426/262 X
4,753,809	6/1988	Webb	426/315 X
4,810,510	3/1989	Lever et al.	426/315 X
4,876,108	10/1989	Underwood et al.	426/650
4,882,184	11/1989	Buckholz et al.	426/262 X
4,968,522	11/1990	Steinke et al.	426/262 X
4,985,261	1/1991	Kang et al.	426/262 X
4,994,297	2/1991	Underwood et al.	426/650
5,013,567	5/1991	Govenius	426/315 X
5,039,537	8/1991	Underwood	426/271
5,292,541	3/1994	Underwood et al.	426/250
5,397,582	3/1995	Underwood et al.	426/250
5,429,831	7/1995	Williams et al.	426/92
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Primary Examiner—Milton Cano

Attorney, Agent, or Firm—Pretty, Schroeder & Poplawski

[57] ABSTRACT

A method of producing a crisp surface and imparting a uniform golden-brown color to a precooked whole muscle meat product by coating at least a portion of the surface of a precooked whole muscle meat product with a browning liquid pyrolysis product. The coated surface is then exposed to an energy source that selectively heats the coated surface of the whole muscle meat product at a temperature and for a time sufficient to develop a golden-brown color on the exposed surface, without substantially shrinking the precooked whole muscle meat product.

36 Claims, No Drawings

EXHIBIT 1

METHOD FOR BROWNING PRECOOKED, WHOLE MUSCLE MEAT PRODUCTS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a method for preparing food products. In particular, it relates to a method for browning precooked, whole meat muscle products.

2. Description of Related Art

There exists a strong consumer demand for precooked, whole muscle meat products, such as precooked meat, poultry, and fish products having the appearance, texture, and taste of products that are naturally smoked or baked or roasted in a home-style oven. For example, consumers place a premium on precooked, whole muscle meat products that have the same golden brown color, crisp surface, and moist interior as their home-cooked counterparts.

While the consumer demand for such precooked products is dramatically increasing because of the products' convenience, consumers also demand that these products be healthful, nutritional, and low in fat. Consequently, to satisfy these sometimes conflicting demands, and to be successful in the marketplace, products must not only have the appearance, texture, and taste of their home-cooked counterparts, but they also must be wholesome.

It has proved especially difficult to prepare precooked, whole muscle meat products, such as precooked deli turkey breasts, chicken nuggets, pork chops, and the like having a golden brown color on a crispy surface. A conventional approach has been to deep fry these products in various kinds of edible seed oils such as cotton seed oil, peanut oil, corn oil, coconut oil, sunflower seed oil, etc. at temperatures in the range of from about 300° to about 450° F. (from about 150° to about 230° C.). Deep frying produces a desirable browning on the surface of the meat product through a reaction known as the Maillard Browning Reaction. The Maillard Browning Reaction takes place when common elements of the food product, such as amino acids, sugars, collagen and even minerals, react in a complex manner. Furthermore, deep frying produces a crisp surface while leaving a moist interior.

There are numerous drawbacks to deep-frying foods, however. They include a residual oily flavor and mouthful, as well as the adverse characterization of the product as being a high fat product, because of the oil that remains embedded in the product's surface. Moreover, the oil can degrade over time, thereby, affecting the product's shelf-life and taste. The use of the high-temperature oil also gives rise to safety concerns, by creating the potential for fires or burns.

Another conventional approach to browning precooked, whole muscle meat products begins with the application to the surface of the meat products of certain browning liquids produced by pyrolyzing wood or cellulose, such as "liquid smokes." The pyrolysis products develop a brown color on the product surface when the coated product is heated for about two hours to about six hours in a batch-type oven at a temperature of from about 120° to about 212° F. (from about 50° to about 100° C.) or for about ten minutes to about forty-five minutes in a circulating air oven or impingement air oven at a temperature from about 250° to about 600° F. (from about 120° to about 320° C.). Useful liquid smoke products are disclosed in Hollenbeck U.S. Pat. No. 3,106,473 and Underwood U.S. Pat. No. 4,876,108. The pyrolysis products, however, impart a smoky taste. Obviously, there

are delicately flavored meat products, such as poultry and fish products, where a smoke flavor is not desired, so that the use of liquid smokes does not provide a viable alternative.

Recently, there have been developed browning liquid pyrolysis products from sugars, such as fructose and dextrose. The smoky taste of the sugar pyrolysis products is greatly reduced, but not always eliminated. These products are described in Underwood U.S. Pat. Nos. 5,397,582, 5,292,541, 5,039,537, and 4,994,297. For example, U.S. Pat. No. 5,397,582 describes coating a precooked sausage and then browning the coated sausage by heating in a microwave oven for about two minutes. While the sausage is browned by the sugar pyrolysis products, the color is not the golden brown associated with products that are naturally smoked or baked or roasted in a home-style oven.

Significant drawbacks remain with the conventional method of browning whole meat muscle products, even with these sugar pyrolysis products. Not only does their residual taste remain factor, but after being heated to temperatures of from about 120° to about 600° F., the meat products lose a significant amount of water that can adversely affect their taste and appearance.

Further, the uniformity of browning obtained the with pyrolysis products and the retention and stability of the brown coating, as well as the color itself, is less than desirable. Still further, because the whole meat muscle products are heated at elevated temperatures for relatively long periods of time, the growth of microbes is facilitated, thus decreasing the shelf-life of the browned whole muscle products. It is a further disadvantage of heating whole meat muscle products at elevated temperatures for relatively long periods of time that large amounts of heat are captured by the product. The product must then be chilled, i.e., the large amount of heat removed. Typically, chilling requires a lengthy, capital-intensive chill tunnel.

Thus, there remains a definite need for an effective method for browning precooked, whole muscle meat products to produce products having the appearance, texture, and taste of their naturally smoked or home-style baked or roasted counterparts. There remains a further definite need for an effective method for crisping and browning the surface of precooked, whole muscle meat products without deep frying. There remains a still further definite need for an effective method for browning mild-flavored or flavorless precooked, whole muscle meat products without imparting a smokey or other unwanted flavor. There remains a still further definite need for an effective method for crisping and browning the surface of precooked, whole muscle meat products that does not cause the products to shrink and their interior to become dried-out. There remains a still further definite need for an effective method for preparing whole muscle meat products having a uniform golden-brown color that is stable and retained throughout the life of the product. There remains a still further definite need for an effective method for crisping and browning a whole muscle meat product that does not adversely affect the shelf-life of the meat product and does not require the removal of great amounts of heat to chill the product. The present invention satisfies these and other needs and provides further related advantages.

SUMMARY OF THE INVENTION

The present invention, which addresses the above needs is embodied in a method of producing a crisp surface and imparting a uniform golden-brown color that is stable and retained throughout the life of a precooked, whole muscle

meat product without imparting an objectionable smoky flavor, without forming an oily surface, without substantially shrinking the meat product, and without adversely affecting the shelf-life of the meat product, but instead, increasing the shelf-life and sensory quality of the product. In some embodiments, a precooked whole muscle meat product, including a poultry product, such as a turkey breast, a chicken breast, or chicken nugget, a ham product, a pork product, or a fish product, is pre-dried to remove free water from its surface. In accordance with the inventive method, at least a portion of the surface of the pre-cooked whole muscle meat product is coated with a browning liquid pyrolysis product. The coated surface is then exposed to an energy source that selectively heats the coated surface of the whole muscle meat product at a temperature and for a time sufficient to develop a golden brown color on the exposed surface, without substantial shrinkage of the precooked, whole muscle meat product.

Suitable energy sources include circulating air ovens, impinging air ovens, laser light sources, medium wavelength energy infra red radiation sources, and sources of microwave radiation. In some embodiments, the energy sources create an environment having a temperature greater than about 60° C. And in some embodiments, the temperature at the core of the meat product is initially less than about 5° C., while after the meat product has been browned, the temperature at the core of the meat product remains at less than about 13° C.

In some embodiments, the browning liquid pyrolysis product is obtained from the pyrolysis of hardwoods or sugars, including dextrose, and from about 0.05 to about 1.0 wt. %, based on the weight of the precooked, whole muscle meat product, of the browning liquid is applied to the surface of the meat product. Also in some embodiments, the browning liquid pyrolysis product contains a masking agent or flavoring enhancing composition. In some embodiments where the whole muscle meat product is a turkey breast, the browning liquid pyrolysis product contains from about 0.5 to about 15 wt. % turkey flavor or turkey broth or a mixture of the two as the masking agent or flavoring enhancing composition.

Other features and advantages of the present invention will become apparent from the following detailed description, which illustrates by way of example, the principles of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Any whole meat muscle product can be advantageously browned in accordance with the invention. Representative whole meat muscle products include poultry, meat, and fish products, such as turkey breasts, chicken breasts, chicken nuggets, ham products, pork products, and the like. The whole meat muscle products can be precooked by any conventional method. Typical methods include initially stuffing a raw whole muscle meat product into a polymeric bag and then sealing the bag. Alternatively, the raw whole muscle meat product is formed in a mold. The raw meat product is then cooked in a smoke house, or steam box, or circulating air oven. After cooking, the whole muscle meat product is chilled by showering with cold water followed by cooling with chilled air to reduce its equilibrium temperature to less than about 40° F. (less than about 5° C.). The thus precooked, chilled, whole muscle meat product is then removed from the polymeric bag or mold.

In some embodiments, the precooked, whole muscle meat product is then placed on a continuously moving conveyor and transported past a series of hot water (e.g., from about 90° to about 212° F.) or steam showers for a period of from about ten to about thirty seconds. The showers remove the gelatin purge formed on the surface of the meat product during cooking. It has been found that the inventive method is more effective if the browning liquid pyrolysis product it applied directly to the surface of the whole muscle meat product and not to an intermediate gelatin layer. Direct application promotes penetration of the browning liquid pyrolysis product into the meat tissue and facilitates the subsequent Maillard Browning Reaction.

After the gelatin purge is removed, the meat product is predried by circulating hot air around the product or by exposing the product to infra-red radiation. It is also been found that when the free water on the surface of the meat product is removed by predrying, the Maillard Browning Reaction is enhanced.

At least a portion of the surface of the thus dried, precooked, whole meat muscle product is then coated with one or more of any suitable browning liquid pyrolysis product, such as the browning liquid pyrolysis products commercially available from Red Arrow Products Company, Inc. Manitowoc, Wis. and described in Hollenbeck U.S. Pat. No. 3,106,473 and Underwood U.S. Pat. Nos. 5,397,582, 5,292,541, 5,039,537, 4,994,297, 4,876,108, which patents are herein incorporated by reference. Products useful in accordance with the inventive method include browning liquids obtained from the pyrolysis of hardwoods such as ST-300 liquid smoke and SELECT 24P liquid smoke both available form Red Arrow Products Company, Inc. Manitowoc, Wis., as well as browning liquids obtained from the pyrolysis of sugars such as MAILLOSE carmel coloring, also available from Red Arrow Products Company, Inc. Manitowoc, Wis.

The concentration of the commercially available products varies depending on the particular browning liquid pyrolysis product, the particular whole muscle meat product to be treated, the particular conditions for the Maillard Browning Reaction, and the desired final color. For example, Maillose is used without any dilution up to about 80 vol. % dilution with water. The higher the concentration of the Maillose or other browning liquid pyrolysis product, the darker golden-brown the final, whole meat muscle product.

In some embodiments, a masking agent or flavoring enhancing composition is included with the browning liquid. For example, in those embodiments where the meat product is a precooked turkey breast, from about 0.5 to about 15 wt. % turkey flavor or turkey broth or a mixture of the two can be added to the browning liquid. Honey and other flavors can also be added to the browning liquid to give a roasted aroma and enhance the flavor of the final product.

The browning liquid is applied to at least a portion of the surface of the precooked, whole muscle meat product by any suitable method, such as by dipping, brushing or spraying. The amount of browning liquid to be applied to the surface will depend on the particular combination of browning liquid, meat product, and color desired. The amount will be readily determinable by one skilled in the art without undue experimentation. Typically, the amount of browning liquid ranges from about 0.05 to about 1.0 wt. %, preferably from about 0.1 to about 0.8 wt. %, and more preferably from about 0.15 wt. % to about 0.3 wt. %, based on the weight of the precooked, whole muscle meat product.

The surface of the meat product is then browned and crisped using an energy source that selectively heats the thus coated surface. In preferred embodiments, the energy source

selectively heats and dehydrates the surface of the meat product by creating an environment having a temperature greater than about 60° C., preferably from about 100° C. to about 290° C., and more preferably from about 150° C. to about 260° C. In those embodiments where the precooked meat product has been kept at its chilled equilibrium temperature of less than about 5° C., the selective heating maintains the core of the meat product at a temperature less than about 13° C., preferably less than about 8° C., and most preferably less than about 5° C.

In one preferred embodiment, the coated meat product is selectively heated and dehydrated using a circulating air oven. In another preferred embodiment, the coated meat product is selectively heated and dehydrated using an impinging air oven. Impinging air ovens cause hot air to be impinged on the top and bottom of the meat product, thereby breaking the boundary layer surrounding the product's surface. Suitable circulating air and impinging air ovens are available from Stein, Inc., Sandusky, Ohio, Convenience Food Systems, Avon, Mass., Heat and Control, Inc., Hayward, Calif., and Procter and Schwartz, Co., Horshau, Pa. Other energy sources for selectively heating and dehydrating the surface of the meat product provide energy in the form of laser light, medium wavelength infra red radiation or microwave radiation.

It has been discovered that the surface of the meat product can be selectively heated and dehydrated by exposing the surface to the energy source for a relatively short length of time. In accordance with the inventive method, a crisp surface having a golden-brown color will develop, without substantial moisture loss of the browned, precooked, whole muscle meat product. In accordance with the inventive process, the moisture loss of the meat product will be less than about 4% and in some embodiments less than about 3% or even less than about 1%, based on the initial weight of the meat product. Consequently, precooked, whole muscle meat products are produced which not only have highly desirable golden-brown color, but have the crisp surface and moist interior associated with naturally smoked or home-cooked products. Furthermore the golden-brown color is uniform and stable and retained throughout the life of the product without imparting an objectionable smoky flavor, without forming an oily surface, without substantially shrinking the meat product, and without adversely affecting the shelf-life of the meat product but instead, increasing the shelf-life and sensory quality of the product.

The following examples are included to further illustrate the invention. They are not limitations thereon.

EXAMPLE 1

A turkey breast was precooked in the following manner. An uncooked turkey breast was injected with a solution containing 82.8 wt. % water, 4.7 wt. % salt, 1.6 wt. % sodium tri-poly phosphate, 7.3 wt. % starch, 2.7 wt. % dextrose, and 0.9 wt. % flavorings. The resulting 36 wt. % injected turkey breast was tumbled and vacuumed packaged in a poly bag, then cooked in a steam box. After chilling to 39.7° F., the bag was removed from the turkey breast; gelatin purge was removed from its surface using a hot water spray; and the turkey was quickly predried using hot air. The precooked, cleaned, and dried turkey breast weighed 6.86 pounds.

A solution containing 300 ml of ST-300 (Red Arrow Co. in Manitowoc, Wis.), 200 ml of Select 24P (Red Arrow Co., Manitowoc, Wis.), and 3600 ml of water was mixed slowly to avoid excess foaming. The resulting browning liquid was applied to the surface of the turkey breast to form a coating weighing 0.03 pounds (0.4 wt. % based on the weight of the uncoated turkey breast).

The coated turkey breast was then placed in a circulating air oven. The turkey breast was browned with for eight minutes with by circulating air heated to 570° F. past both the top and the bottom of the product. The following temperature measurements were recorded:

Temperature before browning 40° F.

Temperature ¼" below surface during browning 104° F.

Temperature 1" below the surface during browning 85 ° F.

Core Temperature after Browning 43° F.

The following color measurements were also recorded for the browned turkey breast using a Hunter Lab Color-Meter:

L*	A*	B*
52.2	9.6	30

The weight of the browned turkey breast was 6.6 pounds, so that the weight loss was about 3.8%.

EXAMPLE 2

A precooked turkey breast was prepared using the procedure of Example 1. The precooked, cleaned, and dried turkey breast weighed pounds.

A browning liquid was then made of 50% (W/W) Maillose (Red Arrow Co., Manitowoc, Wis.) and water. The precooked turkey breast was dipped in the browning liquid for thirty seconds. The surface of the turkey breast picked up 0.02 pounds of this mixture to form a coating (0.3 wt. % based on the weight of the uncoated turkey breast).

The coated turkey breast was then placed in a circulating air oven. The initial temperature of the turkey breast was 40° F. The turkey breast was then browned with air heated to 535° F. circulated past the top, bottom, and sides of the product. A golden brown color was developed within a period of 5–6 minutes. Immediately after browning the core temperature was still 40° F.

The following color measurements were recorded for the browned turkey breast using a Hunter Lab Color-Meter:

L*	A*	B*
50	9.8	30.5

The weight of the browned turkey breast was 6.99 pounds, so that the weight loss during browning was 2.1%.

EXAMPLE 3

A turkey breast was precooked in the following manner. An uncooked turkey breast was injected with a solution containing 82.8 wt. % water, 4.7 wt. % salt, 1.6 wt. % sodium tri-poly phosphate, 7.3 wt. % starch, 2.7 wt. % dextrose, and 0.9 wt. % flavorings. The resulting 45 wt. % injected turkey breast was then tumbled and vacuumed packaged in a poly bag, then cooked in a steam box. After chilling to 39.7° F., the bag was removed from the turkey breast; gelatin purge was removed from its surface using a hot water spray; and the turkey was quickly predried using hot air. The weight of the precooked, cleaned, and dried turkey breast was 9.5 pounds.

The thus prepared turkey breast was submerged for thirty seconds in an undiluted solution of Maillose (Red Arrow Co., Manitowoc, Wis.). The coated turkey breast was then placed in a circulating air oven. The air in the oven was maintained at a temperature of 410° F. The velocity of the air across the coated turkey breast, as measured at the entry zone of the oven, was 3100 feet per minute. The turkey breast was heated for six minutes until a golden-brown color developed. The weight loss after browning was 3%.

The browned product was then chilled in a blast chiller to 40° F. and packaged. The following color measurements were recorded for the browned turkey breast using a Hunter Lab Color-Meter:

L.*	A*	B*
53.2	14.3	39.9

EXAMPLE 4

A turkey breast was precooked using the procedure of Example 1. It weighed 7.56 pounds and had a protein content of 18.7 wt. %, a fat content of 18.9 wt. %, a moisture content of 74.3 wt. %, and a salt content of 1.9 wt. %. Color measurements for the precooked turkey breast were recorded and are reported below.

The precooked turkey breast was submerged for one minute in a browning liquid made of 50% (W/W) Maillose (Red Arrow Co., Manitowoc, Wis.) and water. The coated turkey breast was then exposed to a laser marking system manufactured by Synrad Laser Company, Mukiliteo, Wash. The system had a 130 watt power source, a wave length of 10.6 microns, and a 370 MM. laser lens. The cycle time for the browning was two minutes.

Color measurements for the browned turkey breast were recorded. Following are the Hunter Lab Color-Meter measurements for both the untreated and the browned turkey breast:

	L*	A*	B*
Untreated	82.1	1.5	14.6
Treated	48.9	11.5	29.8

The weight of the browned turkey breast was 7.50 pounds, so that the weight loss during browning was 0.8%

EXAMPLE 5

A turkey breast was precooked using the procedure of Example 1. A browning liquid was prepared by mixing a 50% (W/W) solution of Maillose (Red Arrow Co. in Manitowoc, Wis.) and water with a turkey broth solution, in a volume ratio of 90:10/Maillose solution:turkey broth solution. The mixture was then applied on the surface of the product. A 0.25% pick up was targeted.

This coated turkey breast was then exposed to medium range infra-red radiation energy. The Hunter Lab Color-Meter measurement for the browned turkey breast were L*=57.1; A*=8.8; B*=30.7. The product loss was less than 2%.

While the invention has been described in connection with its preferred embodiments, it will be understood that it is not intended to limit this invention thereto, but it is intended to cover all modifications and alternative embodiments falling within the spirit and scope of the invention as expressed in the appended claims.

I claim:

1. A process for browning precooked, whole muscle meat products comprising:

coating a browning liquid pyrolysis product onto at least a portion of the surface of a precooked whole muscle meat product; and then

exposing the coated surface to an energy source and selectively heating the coated surface of the whole muscle meat product at a temperature and for a time sufficient to develop a golden-brown color on the exposed surface, without substantial shrinking the precooked, whole muscle meat product.

2. The process in accordance with claim 1 wherein the precooked, whole muscle meat product is selected from the group consisting of poultry, meat, and fish products.

3. The process in accordance with claim 2 wherein the precooked, whole muscle meat product is a precooked turkey breast or a precooked chicken breast.

4. The process in accordance with claim 2 wherein the browning liquid pyrolysis product is obtained from the pyrolysis of hardwoods or sugars.

5. The process in accordance with claim 4 wherein the browning liquid pyrolysis product is obtained from the pyrolysis of dextrose.

6. The process in accordance with claim 4 wherein the amount of browning liquid ranges from about 0.05 to about 1.0 wt. %, based on the weight of the precooked, whole muscle meat product.

7. The process in accordance with claim 6 wherein the amount of browning liquid ranges from about 0.1 to about 0.8 wt. %, based on the weight of the precooked, whole muscle meat product.

8. The process in accordance with claim 2 further comprising the browning liquid pyrolysis product contains a masking agent or flavoring enhancing composition.

9. The process in accordance with claim 3 further comprising the browning liquid pyrolysis product contains from about 0.5 to about 15 wt. % turkey flavor or turkey broth or a mixture of the two.

10. The process in accordance with claim 2 wherein the energy source is a circulating air oven, an impinging air oven, a laser light source, a medium wavelength energy infra red radiation source or a source of microwave radiation.

11. The process in accordance with claim 10 wherein the energy source is a circulating air oven or an impinging air oven.

12. The process in accordance with claim 11 wherein the energy source selectively heats the surface of the meat product by creating an environment having a temperature greater than about 60° C.

13. The process in accordance with claim 12 wherein the energy source selectively heats the surface of the meat product by creating an environment having a temperature from about 100° C. to about 290° C.

14. The process in accordance with claim 13 wherein the energy source selectively heats the surface of the meat product by creating an environment having a temperature from about 150° C. to about 260° C.

15. The process in accordance with claim 2 further comprising prior to exposing the meat product to the energy source, the temperature at the core of the meat product is less than about 5° C. and immediately after browning the meat product, the temperature at the core of the meat product is less than about 13° C.

16. The process in accordance with claim 15 wherein prior to exposing the meat product to the energy source, the

temperature at the core of the meat product is less than about 5° C. and immediately after browning the meat product, the temperature at the core of the meat product is less than about 5° C.

17. The process in accordance with claim 1 further comprising predrying the precooked, whole muscle meat product to remove free-water from the product's surface prior to the coating.

18. The process in accordance with claim 2 further comprising predrying the precooked, whole muscle meat product to remove free-water from the product's surface prior to the coating.

19. The process in accordance with claim 6 further comprising predrying the precooked, whole muscle meat product to remove free-water from the product's surface prior to the coating.

20. A process for browning a precooked chicken breast or a turkey breast comprising:

coating at least a portion of the surface of a precooked chicken breast or a precooked turkey breast with from about 0.05 to about 1.0 wt. %, based on the weight of the breast, of a browning liquid pyrolysis product obtained from hardwoods or sugars; and then

selectively heating the coated surface of the breast in an environment having a temperature greater than about 60° C. with energy provided by a circulating air oven, an impinging air oven, a laser light source, a medium wavelength energy infra red radiation source or a source of microwave radiation for a time sufficient to develop a golden-brown color on the coated surface, where the shrinkage of the precooked, whole muscle meat product is less than 4 wt. % based on the initial weight of the meat product.

21. The process in accordance with claim 20 wherein the precooked breast is a precooked turkey breast.

22. The process in accordance with claim 21 wherein the browning liquid pyrolysis product is obtained from the pyrolysis of dextrose.

23. The process in accordance with claim 22 wherein the amount of browning liquid ranges from about 0.15 to about 0.3 wt. %, based on the weight of the breast.

24. The process in accordance with claim 20 further comprising the browning liquid pyrolysis product contains a masking agent or flavoring enhancing composition.

25. The process in accordance with claim 22 further comprising the browning liquid pyrolysis product contains from about 0.5 to about 15 wt. % turkey flavor or turkey broth or a mixture of the two.

26. The process in accordance with claim 23 wherein the energy source is a circulating air oven or an impinging air oven.

27. The process in accordance with claim 26 wherein the energy source selectively heats the surface of the breast by creating an environment having a temperature from about 100° C. to about 290° C.

28. The process in accordance with claim 26 wherein the energy source selectively heats the surface of the breast by creating an environment having a temperature from about 150° C. to about 260° C.

29. The process in accordance with claim 20 further comprising prior to exposing the meat product to the energy source, the temperature at the core of the meat product is less than about 5° C. and immediately after browning the meat product, the temperature at the core of the meat product is less than about 13° C.

30. The process in accordance with claim 28 wherein prior to exposing the meat product to the energy source, the temperature at the core of the meat product is less than about 5° C. and immediately after browning the meat product, the temperature at the core of the meat product is less than about 5° C.

31. The process in accordance with claim 1 wherein the shrinkage of the precooked, whole muscle meat product is less than 4 wt. % based on the initial weight of the meat product.

32. The process in accordance with claim 2 wherein the shrinkage of the precooked, whole muscle meat product is less than 1 wt. % based on the initial weight of the meat product.

33. The process in accordance with claim 21 wherein the shrinkage of the precooked, whole muscle meat product is less than 1 wt. % based on the initial weight of the meat product.

34. The process in accordance with claim 20 further comprising predrying the precooked, whole muscle meat product to remove free-water from the product's surface prior to the coating.

35. The process in accordance with claim 21 further comprising predrying the precooked, whole muscle meat product to remove free-water from the product's surface prior to the coating.

36. The process in accordance with claim 22 further comprising predrying the precooked, whole muscle meat product to remove free-water from the product's surface prior to the coating.

* * * * *

IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF OKLAHOMA

FILED
AUG 19 2002
ROBERT D. DENNIS, CLERK
U.S. DIST. COURT, WESTERN DIST. OF OKLA.
BY _____ DEPUTY

(1) UNITHERM FOOD SYSTEMS, INC., an Illinois corporation; and
(2) JENNIE-O FOODS, INC., a Minnesota corporation,

Plaintiffs,

v.

(1) SWIFT-ECKRICH, INC. d/b/a CONAGRA REFRIGERATED FOODS, a Delaware corporation,

Defendant.

No. CIV-01-347-C

DOCKETED

ORDER

On September 14, 1999, the United States Patent and Trademark Office ("PTO") issued Patent No. 5,952,027 (the "'027 patent") to Prem S. Singh ("Singh"). Mr. Singh filed the '027 patent application with the PTO on May 11, 1998. Mr. Singh subsequently assigned the '027 patent to Defendant Swift-Eckrich, Inc., d/b/a/ ConAgra Refrigerated Foods ("ConAgra"). Plaintiffs Unitherm Food Systems, Inc., and Jennie-O Foods, Inc. ("Unitherm"), have moved this Court to invalidate the '027 patent.

ConAgra, for its part, asks the Court to dismiss the Plaintiffs' causes of action numbered eight (tortious interference with existing contractual and business relations), nine (intentional interference with prospective economic relationships), ten (actual or constructive fraud), eleven (violation of the Sherman Antitrust Act), and twelve (violation of the

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EXHIBIT 2

Oklahoma Antitrust Reform Act). Due to prior Court Order and/or stipulations of dismissal between the parties, a grant of summary judgment for Defendant on the above causes of action would leave the Plaintiffs with one remaining cause of action - a declaration by this Court that U.S. Patent 5,952,027 (the "'027 patent") is invalid and unenforceable.

The Plaintiffs' claim of invalidity and unenforceability is discussed first, as it is from this Court's decision on the validity of the '027 patent that the other claims flow.

*A. **Plaintiffs' Motion for Partial Summary Judgment***

1. Patent Validity

"Under 35 U.S.C. § 282, a patent is presumed valid and one challenging its validity bears the burden of proving invalidity by clear and convincing evidence." *Mas-Hamilton Group v. Lagard, Inc.*, 156 F.3d 1206, 1216 (Fed. Cir. 1998). The Court has previously presumed the '027 patent valid in the hands of its inventor (and assignee) and refused to order a requested transfer of inventorship. However, that does not mean that the patent is indeed valid, it is only presumed so.

Section 102 of U.S.C. Title 35 provides, in relevant part:

> A person shall be entitled to a patent unless --
>
> * * *
>
> (b) the invention was . . . described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Plaintiffs claim that the process disclosed in the '027 patent was on sale and/or in public use in the United States prior to May 11, 1997, and the patent is therefore invalid and unenforceable. To prove their assertion, Plaintiffs must show either "a definite sale or offer for sale of the claimed invention prior to the critical date" or a "public use" of the invention prior to the critical date. *Pfaff v. Wells Electronics. Inc.*, 124 F.3d 1429, 1433 (Fed. Cir. 1997), *aff'd*, 525 U.S. 55 (1998). Here, the critical date is May 11, 1997.

Plaintiffs maintain that David Howard of Unitherm is the true inventor of the process at issue, and that he offered the process for sale prior to May 11, 1997, even repeatedly offering it to the Defendant.[1] From the papers submitted, and as more fully discussed below, it is clear to the Court that David Howard and Unitherm indeed offered a process for sale as early as 1993. However, the question for the Court is whether the process offered by Mr. Howard was identical to the process in the '027 patent. Thus, the Court must examine not only the papers submitted by the parties, but also the patent itself. However, Defendant has objected on admissibility grounds to each of the nearly 80 exhibits attached to the Affidavit of David Howard ("Howard Affidavit") submitted by Plaintiffs in support of their motion. Defendant has moved to strike each of these exhibits. Therefore, before considering them in the context of these motions, the Court must first decide whether the exhibits are admissible.

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[1] However, for the purpose of this motion only, Plaintiffs concede that the process was invented by Defendant, but argue that for this issue it is immaterial.

2. Admissibility

Defendant objects to the exhibits attached to the Howard Affidavit on authentication/hearsay grounds. The Court discusses each of these bars to admissibility in turn below. The motion to strike is contained solely in footnotes to Defendant's response brief. The Court condemns this practice, but, rather than delay the case by requiring the filing of a separate motion and brief, the Court now decides the motion.

a. Authentication

Fed. R. Evid. Rule 901(a) states, in relevant part:

> The requirement of authentication . . . as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims.

Rule 901(b)(1) renders Defendant's objections frivolous as the exhibits are attached to, or are in actuality, sworn affidavits of a "witness with knowledge" that the documents are what they are claimed to be. *Id.* Further, the Amended Howard Affidavit submitted with Plaintiffs' Reply brief remedies any arguable failings of the initial Affidavit. Thus, the Court finds that the documents attached to the Howard Affidavit are properly authenticated.

b. Hearsay

Defendant also attacks many of the exhibits as inadmissible hearsay. Fed. R. Evid. 801. However, the Court agrees with the Plaintiffs' contention that the exhibits fall under the "business records exception" to the hearsay rule found in Fed. R. Evid. 803(6). The Court also agrees that not only are the records of one's own business excepted from the

hearsay rule, but also records received from other businesses, where, as here, the requirements of Fed. R. Evid. 803(6) are met. *United States v. Johnson*, 971 F.2d 562, 571 (10th Cir. 1992). The Court finds that the authenticated exhibits attached to the Howard Affidavit fall under a hearsay exception and are admissible. Thus, the Defendant's Motion to Strike is hereby DENIED.

Having dispensed with the evidentiary objections, the Court now discusses the exhibits submitted by the Plaintiffs to ascertain what "process" may have been developed by David Howard, and what he offered for sale prior to May 11, 1997.

3. Unitherm's "Process"

From the submitted exhibits the Court finds that Unitherm was attempting to sell ovens along with its process for browning and/or smoking muscle meats as early as 1993. Prior to May 11, 1997, the process consisted of the following:

Removing purge material from a pre-cooked whole muscle meat product using hot water, drying the rinsed product prior to applying browning and/or smoking agent by either rapidly conveying the rinsed product through a circulating air oven at 350°C for less than one minute or by using the first zone of the oven for drying and then applying a browning and/or smoking agent between the first and second zones. Browning and/or smoking the product over a range of temperatures (from about 250°C to 350°C) to obtain a spectrum of colors, with product shrinkage of as little as 1% or less. Liquid smoke, Maillose, turkey broth, other flavorants and combinations thereof at overall concentrations of about 20-100% are used.

Some solutions comprising mixtures of broth and Maillose or liquid smoke have broth concentrations of 5%, 10%, and higher. Appendix G, Unitherm's Response to Interrog. Nos. 1, 8; Appendix E, Howard Aff., Exh. 11.

A promotional video ("the Proctor/Unitherm video") filmed September 14, 1993, in Elk Grove, Illinois, includes demonstrations of pre-cooked, whole muscle turkey breasts and hams being, or which have been, dipped in a Maillose or liquid smoke solution and then conveyed through a RapidFlow oven. These products are shown beside a pre-cooked turkey breast that was taken out of the cooking bag and washed and dried, as were the other products, but was not dipped or browned. The video notes that a spray station can be added between oven zones for smoking, flavoring, or enhancing product browning. Appendix E, Howard Aff. ¶¶ 14-18, Exhs. 12A-G, 13, 81.

Importantly for this case, the Unitherm process was demonstrated to Syed Hussain, who was present on behalf of Defendant, at a "test" conducted on September 30, 1993, at Unitherm's facility. Plaintiff's Brief at 8, citing Appendix B, Defendant's Answer ¶ 14. Defendant admits that the "tests" involved applying Maillose to the surface of a fully cooked turkey breast and then conveying the breast through a RapidFlow circulating air oven at 280-300° C for 7 minutes. *Id.*

Unitherm data dated October 14, 1993, indicates "five different runs" were made at the behest of Defendant with dip times of one minute in solutions ranging from 50% to 5%. "Internal core temperatures were all 36° F (2° C) or less, with none increasing more than 3°

F (1-1/2° C). Yields of up to 98.7% were obtained." Plaintiff's Brief at 9; *citing* Howard Aff., Exh. 25. Defendant argues that the "runs" were made in the interest of Unitherm selling, not a process, but ovens to Defendant. In fact, Defendant alleges that it had earlier disclosed the process at issue to Unitherm. Plaintiffs' Brief at 9; citing App. B, Def's. Answer ¶¶ 12-14. However, this assertion is belied by the testimony of Messrs. Hussain and Singh - that they do not know how Unitherm "derived the concept of using liquid browning agent or liquid smoke in conjunction with the RapidFlow oven to brown whole muscle turkey products." Plaintiffs' Brief at 9 n. 6, citing App. J, Singh Dep. pp. 146-47; App. X, Hussain Dep. pp. 115-16, 158.

From October 26 to December 1, 1993, copies of the Proctor/Unitherm video were distributed, primarily by mail and at trade shows, throughout the industry. Transmittals and related letters accompanying the videos variously discuss: "the next generation of turkey browning systems;" successful uniform browning using Maillose; yields of 98-99%; processing times under eight minutes; application of Maillose by drenching, submersion, or between cooking zones; "the 'browning' process;" and an internal temperature rise of less than 1°C. *Id.*, Howard Aff., Exhs. 15-20. One letter states that the items in the video were processed in about seven minutes. *Id.*, Exh. 18.

Unitherm did not, and never intended to, patent the process at issue.

4. Summary Judgment Standard

Summary judgment is appropriate if the pleadings and affidavits show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "[A] motion for summary judgment should be granted only when the moving party has established the absence of any genuine issue as to a material fact." *Mustang Fuel Corp. v. Youngstown Sheet & Tube Co.*, 561 F.2d 202, 204 (10th Cir. 1977). The movant bears the initial burden of demonstrating the absence of material fact requiring judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A fact is material if it is essential to the proper disposition of the claim. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The critical question here is whether there is clear and convincing evidence that Defendant patented a process on May 11, 1998, that was on sale and/or in public use before May 11, 1997. As stated above, if the answer is affirmative, the Defendant's patent is invalid and unenforceable. The Court must first construe the claims of the '027 patent to discern whether Mr. Singh should have been barred from patenting this invention.

5. Claims

In order to assess the "metes and bounds" of a patent, it is the Court's role to interpret and construe the patent's claims. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970, 997 (Fed. Cir. 1995). "When a court construes the claims of the patent . . . the court is defining the federal legal rights created by the patent document." *Id.* at 978. As repeatedly

stated by the Federal Circuit and the Supreme Court, the Court is the sole arbiter of claim construction. *See Markman* at 977. "'To ascertain the meaning of claims, [the Court] consider[s] three sources: the claims, the specification, and the prosecution history.'" *Markman* at 979, *quoting Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1561 (Fed. Cir. 1991). "[I]deally there should be no 'ambiguity' in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history." *Markman* at 986. In this case the prosecution history of the '027 patent has not been submitted; thus, the Court relies solely on the claims and the specification for its construction of the '027 patent claims.

The Court has been made aware of a recent case, *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728 (Fed. Cir. 2002), where the court held that Orange Bang did not "present substantial evidence satisfying its clear and convincing burden of proof that it . . . practiced" a "complete embodiment[] of the claimed invention." *Id.* at 738. The court further stated the general proposition that "oral testimony of prior public use must be corroborated in order to invalidate a patent." *Id.* at 737-38. Here, because of the Court's ruling that the submitted documentary evidence is admissible, there is voluminous corroborating evidence accompanying the deposition testimony in this case. Thus, the Court's task is to discern whether Unitherm practiced a complete embodiment of the invention claimed in the '027 patent prior to May 11, 1997.

The '027 patent includes 36 claims (2 independent and 34 dependent) and is entitled: *Method for Browning Precooked, Whole Muscle Meat Products.* The first independent claim (1) is for:

> A process for browning precooked, whole muscle meat products comprising: coating a browning liquid pyrolysis product onto at least a portion of the surface of a precooked whole muscle meat product; and then exposing the coated surface to an energy source and selectively heating the coated surface of the whole muscle meat product at a temperature and for a time sufficient to develop a golden-brown color on the exposed surface, without substantial shrinking the precooked, whole muscle meat product.

'027 patent, col. 8, ll. 4-14.

The rest of the claims are variations on the theme of Claim 1, utilizing different heat source temperatures (about 60° C. - about 290° C.), core meat temperatures (less than 5° C. - 13° C.), shrinkage (less than 1 - 4 wt. %), products (turkey, chicken, fish), browning liquid pyrolysis products (hardwood, sugar, dextrose), amount of browning product (.05 - 1.0 wt. %), masking agents or flavoring enhancing compositions, utilizing turkey flavor and/or broth in the browning liquid pyrolysis product (.5 - 15 wt. %), and energy sources (circulating air oven, impinging air oven, laser light, medium wavelength energy infra red radiation or microwave radiation). The Plaintiffs' chart of the parallels between the Unitherm process and the '027 patent succinctly demonstrates that the two "inventions" are one and the same. Plaintiffs' Brief at 28. Thus, the Court finds that the '027 patent describes the Unitherm process prior to May 11, 1997.

Defendant's only rebuttals are disputed interpretation of the claim terms "golden brown" and "browning liquid pyrolysis product," and that David Howard never publicly used or offered the Unitherm process for sale. These are discussed in turn below.

6. Golden Brown

To begin, the '027 patentee did not act as his own "lexicographer" and failed to specifically define the term "golden brown." *Rexnord Corp. v. The Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001), 2001 U.S. App. LEXIS 24810, *11 ("patent law permits the patentee to choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning"). Thus, the Court views the term "golden brown" with its plain meaning to one of skill in the art. *Talbert Fuel Sys. Patents Co. v. Unocal Corp.*, 275 F.3d 1371 (Fed. Cir. 2002), 2002 U.S. App. LEXIS 241 *7, *supra.* "Golden brown" is defined as "a variable color averaging a strong brown that is yellower and slightly darker than gold brown, yellower and paler than average russet, and yellower and less strong than rust." *Webster's Third New International Dictionary*, 975 (1986).

Defendant argues that "a determination of 'golden brown' under the '027 Patent necessitates a Hunter-Lab Color Meter measurement of the L, A and B values of that product." Defendant's Response at 40. Defendant further asserts that *examples* in the specification limit the term golden brown to color measurements ranging from L= 48.9-53.2; A=9.6-14.3; and B=29.8-39.9. However, "courts cannot alter what the patentee has chosen

to claim as his invention. . . limitations appearing in the specification will not be read into claims, and. . . interpreting what is *meant* by a word *in* a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.'" (emphasis in original). *Intervet America, Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989), *quoting E.I. Du Pont De Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). "'[C]ourts do not rework claims. They only interpret them.'" *Id.*, *quoting Autogiro Co. of America v. United States*, 384 F.2d 391, 395-96 (Ct. Cl. 1967). The Court has "set forth the asserted claim[] in full above and it is clear that [it] make[s] no reference whatever to [limiting "golden brown" to LAB color measurements]." *Id.* at 1055.

The Court thus disagrees with Defendant's unsupported assertion that "golden brown" is defined in the '027 patent. The Court finds that the specification only makes clear that the inventors used language such as: "The following examples are included to further illustrate the invention. *They are not limitations thereon*" (emphasis added). '027 patent, col. 5, ll. 48-49. The patentee had every opportunity to define by limit the term "golden brown" and chose not to do so. The Court finds that the closest thing to a definition of golden brown in the '027 patent appears at col. 1, ll. 15-18, "consumers place a premium on precooked, whole muscle meat products that have the same golden brown color . . . as their home-cooked counterparts." The Court further finds that documents submitted by Plaintiffs, e.g. Howard Aff., Exhs. 1E, 44C, and 44F, clearly encompass a "golden brown" product.

Finally, Defendant's expert in sensory evaluation declares that "no system or test has been used to verify that the color computer printouts attached . . . to Plaintiffs' Motion . . . accurately reflect the color of a product with certain L, A and B values." Defendant's Response, Exh B, p. 2. However, because the Court finds that LAB values do not limit the term golden brown in the '027 patent, the assertion is irrelevant.

7. Browning Liquid Pyrolysis Products

Defendant also claims that Plaintiffs misconstrue the phrase "browning liquid pyrolysis product" by relying on the application of liquid smoke. Defendant states that there are a number of liquid smoke products that do not promote browning and those products are thus not browning liquid pyrolysis products as defined in the '027 patent. The Court finds that the term is not, as Defendant asserts, defined in the '027 patent. Second, the Court notes that there are other pyrolysis products which do not promote browning. However, it is undisputed that Unitherm sometimes used a browning liquid smoke product, which is a browning liquid pyrolysis product. Importantly, Unitherm's process also uses Maillose as a browning agent. Maillose is not liquid smoke but is undisputedly also a browning liquid pyrolysis product. The Court finds it enough that at least two such browning liquid pyrolysis products, as called for in the '027 patent, were used.

8. Public Use/On-Sale Bar

In *Pfaff v. Wells, supra,* the Supreme Court elucidated a two-part test for an on-sale bar: 1) the product must be the subject of a commercial offer for sale; and 2) the invention

must be ready for patenting. 525 U.S. at 67-68. Here, the Plaintiffs have stated undisputed facts which show, as a matter of law, that the Unitherm process was on-sale and ready for patenting as early as 1993. The Defendant argues that *it* did not sell or use the process in the '027 patent prior to the application cut-off date. While that may be true, the undisputed fact is that it was demonstrated and offered by Unitherm for sale to the Defendant. Therefore, the fact that it wasn't Defendant who made a public use or sale of the process is irrelevant. Even if Mr. Singh did invent the process at issue, it was unpatentable due to Unitherm's offer for sale prior to May 11, 1997. The correspondence between Unitherm and the Defendant establishes this finding as their co-existence in relation to a potential sale of the Unitherm process goes back at least to 1993.

Further, the fact that Unitherm sold its process to Hudson Foods and that Hudson Foods had product, produced by the Unitherm process, on the market by April 1997 is undisputed. Plaintiffs' Brief, Exh. N. Defendant stresses that Unitherm sold Hudson an oven, not a process. Hudson's representative claims that the process was in fact *Hudson's* and they purchased Unitherm's oven because, "they [Unitherm] had an oven . . . that would do this [in-line smoking and/or browning] better in this particular application." Exh. N at 159. It is undisputed that the "basic process [utilized by Hudson] was the same [as David Howard's]. Exh. N at 244. "[T]he primary change . . . was the addition of a conveyor system that took it through a [RapidFlow] oven." *Id.*

The Court finds Hudson's test data to reveal that after purchasing and utilizing Unitherm equipment, Hudson practiced a complete embodiment of the invention claimed in the '027 patent in February, 1997. See Exh. N at WB-000081-85. For illustration, the Court inserts the Hudson data parenthetically within Claim 1 of the '027 patent:

> A process for browning precooked, whole muscle meat products (breasts) comprising: coating a browning liquid pyrolysis product (liquid smoke, MAILLOSE from 45 seconds to 70 seconds) onto at least a portion of the surface of a precooked whole muscle meat product; and then exposing the coated surface to an energy source (Unitherm 3-zone RapidFlow oven) and selectively heating the coated surface of the whole muscle meat product at a temperature and for a time sufficient to develop a golden-brown color (299° C. - 354° C. at 7m. 48 s. - 9m 30s. resultant colors from "dark" to "golden brown with black highlights")[2] on the exposed surface, without substantial shrinking (1.7 - 3.16%) the precooked, whole muscle meat product.

'027 patent, col. 8, ll. 4-14.

The Court finds the above to be clear and convincing evidence that the Unitherm process, patented by the Defendant, was on-sale and in use (by perhaps more than one company), prior to May 11, 1997.

Defendant repeatedly stresses to the Court that Unitherm's attempts to sell its process were confidential and thus not public. The Defendant misapplies the law of public use. The

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[2] The Court notes that the temperature of 299° C. is higher than the upper range of 290° C. in the '027 patent. However, the Court also notes that the temperature in Example 1 of the '027 patent was 570°F. which converts to a temperature of 299° C. Further, the process offered for sale by Unitherm utilizes oven temperatures ranging from 250°-350° C. The undisputed "key" to the process of in-line browning and/or smoking is a calculus of temperature over time that results in the desired golden brown end-product.

purpose of the public use bar is "to require *inventors* to assert with due diligence *their* right to a patent through the prompt filing of a patent application." *LaBounty Mfg. v. U.S. Intern. Trade Com'n*, 958 F.2d 1066, 1071 (Fed. Cir. 1992) (emphasis added). Defendant correctly asserts the proposition that "third party secret commercial activity . . . [should not act as] a [public use] bar [against ConAgra]." *Woodland Trust v. Flowertree Nursery*. 148 F.3d 1368, 1371 (Fed. Cir. 1998). This is to protect patentees from losing their patent rights when a third party has also practiced the invention at issue, without the patentee's knowledge. This is not the case here. It is undisputed that employees for Defendant were aware of the technology as early as 1993. It is also undisputed that Hudson Foods purchased technology from Unitherm in February 1997, and a mass mailing of videos and associated correspondence, regardless of David Howard's expectations of secrecy, resulted in the public distribution and offer for sale of the Unitherm process. It is absurd to argue that the technology was somehow "secret." *See OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1402 (Fed. Cir. 1997) ("secret prior art [is] art that has been abandoned, suppressed, or concealed"). The undisputed facts establish, as a matter of law, that "secret" prior art does not exist in this case and does not bar application of § 102(b).

The Court has closely examined the voluminous documentation submitted in connection with the present motions and concludes that the Defendant's patent describes a process that was both on sale and in public use prior to May 11, 1997. Thus, the Court finds the 1999 issuance of the '027 patent was in error. Because the Court finds the '027 patent

to be invalid and unenforceable, it is not necessary to discuss the Plaintiffs' allegations of Defendant's fraud on the Patent Office. The Court now examines the remaining causes of action in turn, as the Defendant has moved for summary judgment on each.

B. Defendant's Motion for Summary Judgment

1. Anitrust Violations

Defendant argues that the two Plaintiffs' antitrust claims cannot succeed for different reasons: 1) Unitherm is not a competitor of the Defendant in the market for sliceable cooked turkey products; and 2) Jennie-O cannot show any antitrust injury as a result of any action of the Defendant. The Court agrees only with the latter and discusses each argument separately below.

a. Unitherm

The Sherman Act § 2 states, in relevant part:

> "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony."

15 U.S.C. § 2.

The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

The Clayton Act states, in relevant part:

> "[A]ny person who shall be injured in his business . . . by reason of anything forbidden in the antitrust laws may sue therefor . . . without respect to the amount in controversy, and shall recover threefold the damages by him sustained. . . ."

15 U.S.C. § 15.

ConAgra argues that Unitherm cannot succeed on its antitrust claims because Unitherm is not a competitor of ConAgra and thus has no antitrust standing. The Court finds that the law is not as ConAgra argues it to be.

In *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965), the Supreme Court held that "the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present. In such event the treble damage provisions of § 4 of the Clayton Act would be available to an injured party." *Id.* at 174.

ConAgra denies that it is a competitor of Unitherm, claiming that ConAgra processes meat while Unitherm sells ovens. But it is undisputed that ConAgra offers a browning/smoking process at a royalty of 10¢ per pound and Unitherm offered its browning/smoking process for sale as early as 1993. And ConAgra's own documents previously produced in this action also support the conclusion that ConAgra is a competitor of Unitherm and that ConAgra is enforcing its patent.

> Others in the industry may approach your company regarding this patent, and we would appreciate it if you would inform them

> that we intend to aggressively protect all of our rights under this patent.

Plaintiffs' Brief in Opposition, Exhibit 9 (Letters from ConAgra to 15 prospective purchasers of the Unitherm system).

This Court has already found the reference to "others in the industry" sufficient to put Unitherm under apprehension of a lawsuit for patent infringement -- something which has since come to fruition with the filing of ConAgra's counterclaim. The fact that ConAgra has asserted a counterclaim for patent infringement on an invalid patent makes Unitherm's antitrust claim a viable one. *Walker Process*, 382 U.S. 172. The issue yet to be decided is whether ConAgra fraudulently obtained the patent. *See Walker Process, supra.* Thus, the Court finds that the undisputed facts are sufficient to withstand the motion for summary judgment on Unitherm's antitrust claims.[3]

b. Jennie-O

ConAgra next argues that Jennie-O's antitrust claims must be dismissed because Jennie-O cannot show antitrust injury. Jennie-O's theory of antitrust recovery differs from that of Unitherm. Jennie-O alleges a right to seek injunctive relief for prospective damage under § 16 of the Clayton Act. *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 260-61 (1972), permits suit for threatened damage:

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[3] Because the Court has upheld Unitherm's antitrust causes of action under federal law, a discussion of the Oklahoma Antitrust Reform Act ("OARA") 79 Okla. Stat. § 205, is unnecessary. *See* 79 Okla. Stat. § 212 ("[OARA] shall be interpreted in a manner consistent with Federal Antitrust Law, 15 U.S.C. § 1, *et seq.* and the case law applicable thereto").

> [Section] 16 of the Clayton Act, 15 U. S. C. § 26 which provides for injunctive relief [states, in relevant part]: "Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws . . . when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity, under the rules governing such proceedings . . . ."

Here, Jennie-O alleges that enforcement of fraudulently obtained monopoly rights in the '027 patent by requiring a 10¢ per pound royalty would "drive Jennie-O out of business." However, because the '027 patent is invalid, Jennie-O's standing to participate in a cause of action for prospective injunctive relief due to Defendant's alleged violations of the antitrust laws is moot. Jennie-O cannot be driven out of business by a competitor attempting to charge royalties on an invalid patent.

2. Tortious Interference with Existing Contractual or Business Relations

Under Oklahoma law, "one has the right to carry on and prosecute a lawful business in which he is engaged without unlawful molestation or unjustified interference from any person, and any malicious interference with such business is an unlawful act and an actionable wrong." *Crystal Gas Co. v. Oklahoma Natural Gas Co.*, 1974 OK 34, 529 P.2d 987, 989.

To recover damages for the tort of malicious interference with a business relationship, a plaintiff must show:

1. That he or she had a business or contractual right that was interfered with.

2. That the interference was malicious and wrongful, and that such interference was neither justified, privileged nor excusable.

3. That damage was proximately sustained as a result of the complained-of interference.

Mac Adjustment, Inc. v. Property Loss Research Bureau, 1979 OK 41, 595 P.2d 427, 428.

Defendant correctly asserts that there must be more to a business relationship than speculation on the part of David Howard that he could have begun business relationships with new purchasers of the Unitherm process. The Court finds that Unitherm has not adduced material facts, other than the self-serving and unsubstantiated testimony of David Howard, that place this cause of action in dispute. Indeed, Unitherm has not expressly responded to this portion of Defendant's brief, instead arguing a right to proceed on its claim of Intentional Interference with Prospective Economic Advantage. Thus, the cause of action for Tortious Interference with Existing Contractual or Business Relations must fail.

3. Interference with Prospective Economic Advantage

The parties' briefs treat the tort of interference with business relations as synonymous with the tort of interference with prospective economic advantage. "This comparison is not entirely accurate. Although both torts do have similarities, the underlying theories of liability differ. Interference with a prospective economic advantage usually involves interference with some type of reasonable expectation of profit, whereas interference with a contractual relationship results in loss of a property right." *Overbeck v. Quaker Life Ins. Co.*, 1984 OK CIV APP 44; 757 P.2d 846, 847-48. Taking all circumstances in their totality, the Court

finds that there exist enough disputed facts to support this cause of action through the summary judgment stage.

It is undisputed that once the '027 patent issued, the Defendant mass mailed an arguably threatening letter throughout the industry. It is also the testimony of Robert Wood of Jennie-O that this letter had, at the least, a chilling effect on any further possibility of Unitherm selling its products to Jennie-O. Plaintiffs' Brief, Exh. 5, pp. 74-76. The Court thus finds that the cause of action for interference with prospective economic advantage is not susceptible to summary judgment.

4. Actual or constructive fraud

Defendant claims that Unitherm cannot prove fraud because Unitherm has failed to identify a material omission or misrepresentation made by the Defendant to Unitherm. The Court disagrees and denies summary judgment on this cause of action.

The Court notes that:

> Oklahoma follows the view that fraud can be predicated upon a promise to do a thing in the future when the intent of the promisor is otherwise. This principle is an *exception* to the general rule that for a false representation to be the basis of fraud, such representation must be relative to existing facts or those which previously existed, and not as to promises as to future acts.... The gist of the rule is not the breach of promise but the fraudulent intent of the promisor at the time the pledge is made not to perform the promise so made and thereby deceive the promisee. There is a wide distinction between the nonperformance of a promise and a promise made *mala fide*, only the latter being actionable fraud.

Citation Co. Realtors, Inc. v. Lyon, 1980 OK 68, 610 P.2d 788, 790-91 (emphasis added), *citing State ex rel. Southwestern Bell Telephone Co. v. Brown*, 1974 OK 19, 519 P.2d 491.

Unitherm claims that ConAgra promised to consider the purchase of the Unitherm process which was first shown to ConAgra in 1993, and ConAgra then stole the process and patented it for its own use. ConAgra vigorously disputes this claim. The undisputed facts are that the Defendant considered purchasing Unitherm's technology and failed to do so. Under Oklahoma law, the disputed fact that the Defendant may have subsequently stolen Unitherm's technology supports a cause of action for breaching a promise to consider a purchase. The Court DENIES summary judgment on this count.

CONCLUSION

As discussed more fully above, Defendant's Motion to Strike is hereby DENIED. Plaintiffs are GRANTED partial summary judgment on their third cause of action and their sixth and seventh affirmative defenses to Defendant's Counterclaim (Patent Invalidity and Unenforceability). Plaintiffs are entitled to a judgment declaring the '027 patent invalid and unenforceable.

Defendant is GRANTED summary judgment on the Plaintiffs' eighth cause of action (tortious interference with existing contractual and business relations). Defendant is also GRANTED summary judgment on Jennie-O's antitrust claims.

Defendant's Motion for Summary Judgment is denied on remaining causes of action, i.e., intentional interference with prospective economic relationships, actual or constructive fraud, violation of the Sherman Antitrust Act (Unitherm only).

Finally, this ruling moots the Defendant's motion to strike Jennie-O's second affirmative defense of non-infringement, or, in the alternative, for partial summary judgment of infringement. A judgment will enter at the conclusion of these proceedings.

IT IS SO ORDERED this 19th day of August, 2002.

ROBIN J. CAUTHRON
CHIEF UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

UNITHERM FOOD SYSTEMS, INC., and JENNIE-O FOODS, INC., now known as JENNIE-O TURKEY STORE, INC.,	)	FILED MAR 27 2003 U.S. DIST. COURT WESTERN DIST. OF OKLA BY _____ DEPUTY
Plaintiffs,	)	
v.	)	Case No. CIV-01-347-C
SWIFT-ECKRICH, INC. d/b/a CONAGRA REFRIGERATED FOODS,	)	
Defendant.	)	

JUDGMENT

This action came on for trial before the court and a jury, Honorable Robin J. Cauthron, Chief Judge of the United States District Court, presiding. The issues having been duly tried and the jury has duly rendered its verdict. In accordance with the jury's March 19, 2003 verdict,

IT IS ORDERED, ADJUDGED AND DECREED that Plaintiff Unitherm Food Systems, Inc. ("Plaintiff") shall have and recover on its claims against Defendant Swift-Eckrich, Inc. d/b/a ConAgra Refrigerated Foods ("Defendant"), as follows:

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EXHIBIT 3

On Plaintiff's claim for attempted monopolization in violation of § 2 of the Sherman Act, trebled pursuant to 15 U.S.C. § 15, the sum of Eighteen Million and No/100 Dollars ($18,000,000.00);

On Plaintiff's claim for tortious interference with prospective economic advantage, the sum of Two Million and No/100 Dollars ($2,000,000.00);

On Plaintiff's claim for exemplary damages the sum of Two Million and No/100 Dollars ($2,000,000.00);

IT IS THEREFORE ORDERED, ADJUDGED AND DECREED that Plaintiff shall have and recover judgment against the Defendant in the amount of Eighteen Million and No/100 Dollars ($18,000,000.00) and post-judgment interest thereon at the rate provided by law, a reasonable attorney fee and the costs of this action.

Entered this 27th day of March, 2003.

Robin J. Cauthron
United States Chief District Judge

ENTERED ON JUDGMENT DOCKET ON MAR 27 2003

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

FILED

APR 09 2003

ROBERT D. DENNIS, CLERK
U.S. DIST. COURT, WESTERN DIST. OF OKLA
BY _____, DEPUTY

UNITHERM FOOD SYSTEMS, INC., an Illinois corporation; and JENNIE-O FOODS, INC., a Minnesota corporation,	)	
Plaintiffs,	)	
v.	)	Case No. CIV-01-347-C
SWIFT-ECKRICH, INC. d/b/a CONAGRA REFRIGERATED FOODS, a Delaware corporation,	)	
Defendant.	)	

JUDGMENT

Based upon the Stipulation of the Plaintiffs and Defendant, and pursuant to U.S.C. § 15, IT IS ORDERED, ADJUDGED AND DECREED that Plaintiffs have and recover judgment against the Defendant in the amount of $1,022,445 as a reasonable attorney fee.

Entered this 9 day of April 2003.

Robin J. Cauthron
United States District Judge

199744.1

ENTERED ON JUDGMENT DOCKET ON 4-9-03

EXHIBIT 4

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EXHIBIT 5

Prepackage Surface Pasteurization of Ready-to-Eat Meats with a Radiant Heat Oven for Reduction of *Listeria monocytogenes*

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MS 02-427: Received 26 November 2002/Accepted 26 March 2003

ABSTRACT

In this paper, a thermal process for the surface pasteurization of ready-to-eat (RTE) meat products for the reduction of *Listeria monocytogenes* on such products (turkey bologna, roast beef, corned beef, and ham) is described. The process involves the passage of products through a "tunnel" of heated coils on a stainless steel conveyor belt at various treatment times relevant to the manufacture of processed meat for the surface pasteurization of RTE meat products. Two inoculation procedures, dip and contact inoculation, were examined with the use of a four-strain cocktail of *L. monocytogenes* prior to heat processing. With the use of radiant heat prepackage surface pasteurization, 1.25 to 3.5-log reductions of *L. monocytogenes* were achieved with treatment times of 60 to 120 s and air temperatures of 475 to 750°F (246 to 399°C) for these various RTE meats. Reduction levels differed depending on the type of inoculation method used, the type of product used, the treatment temperature, and the treatment time. Prepackage pasteurization (60 s) was also combined with postpackage submerged water pasteurization for formed ham (60 or 90 s), turkey bologna (45 or 60 s), and roast beef (60 or 90 s), resulting in reductions of 3.2 to 3.9, 2.7 to 4.3, and 2.0 to 3.75 log cycles, respectively. These findings demonstrate that prepackage pasteurization, either alone or in combination with postpackage pasteurization, is an effective tool for controlling *L. monocytogenes* surface contamination that may result from in-house handling.

Listeria monocytogenes is a significant foodborne pathogen that is capable of causing foodborne illnesses that may simulate flulike conditions (i.e., listeriosis). Serious infections can further lead to abortions in pregnant women and meningitis. Mortality rates can reach 25 to 30% overall in large outbreaks and may even be as high as 50% (septicemia) to 70% (meningitis) for primary infected individuals or >80% for perinatal-neonatal infections. Consequently, both the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) and the U.S. Food and Drug Administration (FDA) have issued a zero tolerance for this pathogen in ready-to-eat (RTE) foods, declaring it an "adulterant" and "added agent" harmful or injurious to consumers *(15)*.

L. monocytogenes is widespread in the environment and has been found in plants, soil, animals, water, silage, and other processing environment sources. The organism is heat and salt tolerant, can form biofilms on food processing equipment *(10)*, and has the ability to grow at refrigeration temperatures. Like many animal-associated pathogens, *L. monocytogenes* can gain entry into meat processing facilities through contaminated carcasses and/or boxed beef, poultry, or other meats *(14)*. Epidemiological studies indicate that *L. monocytogenes* is often transferred through cross-contamination from employees, drains, standing water, residues, floors, and food contact surfaces, suggesting that a finished RTE product can readily acquire *L. monocytogenes* contamination prior to final packaging while the product is exposed to environmental contamination *(9, 12)*. Thus, sanitation programs are critical in controlling the pathogen in processing environments.

Foods typically associated with listeriosis are foods that are highly processed and have an extended shelf life, foods such as RTE processed meats *(6)*. *L. monocytogenes* can be found in the environments of food processing facilities, and therefore its elimination from these types of facilities is of particular concern to manufacturers of RTE meats. Alarmingly, the results of USDA-FSIS RTE meat sampling program from 1998 to 2001 showed *L. monocytogenes* incidence rates of 5.7% for sliced luncheon meats, 4.4% for small-diameter sausages (hot dogs), and 3.1% for cooked roast beef. Since being labeled as an adulterant of RTE foods, *L. monocytogenes* has been involved in numerous product recalls, foodborne illnesses, and even deaths due to the consumption of contaminated RTE meat products *(1–3)*. One of the largest outbreaks arising from postprocessing contamination of RTE meats, occurring in 1998, involved a large manufacturer of hot dogs and luncheon meats and resulted in 21 deaths and >100 illnesses in 14 states, leading to the recall of 35,000,000 lb of hot dogs and deli meats *(1, 2)*.

Postprocessing contamination of RTE meats with *L. monocytogenes* has become a major concern to the value-added processed-meat industry, and surface pasteurization is becoming an effective means for reducing the risk posed by such products. Much of the research on meat surface pasteurization has been related to steam pasteurization (i.e.,

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Frigoscandia, Inc., a manufacturer of equipment for surface pasteurization using steam) of exposed raw beef carcass surfaces to reduce the incidence of *Escherichia coli* O157:H7 that might end up in trimmings and ground beef *(4)*. The *Listeria* problems currently encountered in the RTE processed meat industry are the result of a combination of (i) *Listeria* contamination from the processing environment and from workers and (ii) a high degree of postprocessing product exposure to potential contamination sources and handling practices that could allow incidental surface contamination (worker handling, removal of deli products from cook-in bags, exposed product on trays or carts wheeled into smokehouses, etc.). Various technologies and approaches to help reduce the risk of postprocessing contamination have emerged, including chemical-antimicrobial treatments *(5, 11, 13)*, irradiation (not yet approved for RTE meats) *(16)*, and thermal processes such as postpackage submerged water pasteurization *(7, 8)*. These techniques can be used either individually or in combination to produce a "hurdle" effect on pathogen contaminants. To provide a solution to this problem, we have been studying surface pasteurization as a convenient and effective means of reducing incidental contamination on product surfaces immediately before (prepackage) or after (postpackage) final packaging. Postpackage pasteurization *(7)* has already been implemented by several large meat processors. The objective of this work was to investigate the effectiveness of a radiant heat oven for the prepackage surface pasteurization of RTE deli meats as a means of controlling *L. monocytogenes* on fully cooked meat products (turkey bologna, deli ham, corned beef, and roast beef).

MATERIALS AND METHODS

Bacterial strains. A mixture of four strains of *L. monocytogenes* (Scott A-2, serotype 4b; V7-2, serotype 1/2a; 39-2, retail hotdog isolate; 383-2, ground beef isolate) was used for the inoculation trials. These strains were made resistant to streptomycin (100 μg/ml; Sigma Chemical Co., St. Louis, Mo.) and rifamycin S/V (10 μg/ml; Sigma) and were plated on general-purpose agar (tryptic soy agar [TSA]; Difco, Becton-Dickinson, Franklin Lakes, N.J.) containing these antibiotics when they were selectively plated for the inoculum cultures. This approach allows the recovery of viable and heat-injured cells without the need for harsh selective media that may prevent the growth of heat-injured cells (e.g., modified Oxford agar) or in lieu of indigenous contaminating bacteria. For the culturing of the bacterial strains, 100 μl of thawed frozen culture was transferred to 10 ml of brain heart infusion (BHI) broth and incubated overnight at 30°C; each of the four cultures was then transferred individually to 40 ml of BHI culture and later combined (for a total volume of 160 ml) prior to their use in the dip inoculation treatment. For surface contact inoculation, overnight cultures were mixed in equal proportions, and the mixture (100 μl) was surface plated onto tryptic soy agar (TSA) that was held overnight at 30°C.

Product inoculation. Samples of roast beef (whole and split rounds), corned beef (whole logs), and ham (formed and whole muscle) generally weighed 4 to 13 lb (1.8 to 5.9 kg), and turkey bologna samples were composed of ~2-lb sections. Except for two lots of roast beef (received frozen and allowed to thaw), all products were received fresh and refrigerated from commercial processors as they would normally be shipped for sale to retailers without the additional thermal processing. The products were stored at 3°C (37.4°F) upon receipt and were removed from refrigerated storage just prior to inoculation, so the internal temperature was the same. Immediately before they were used, products were taken from refrigerated storage, removed from their packaging wrap, and inoculated with *L. monocytogenes* by the dip inoculation method or by a contact inoculation method. Control samples were also inoculated for each replication trial but were not heated; these samples were used to determine the basal recovery level for the inoculated microorganisms.

For the dip inoculation method, ca. 160 ml of a four-strain mixture (i.e., 4 × 40 ml) of *L. monocytogenes* was placed in a stainless steel bowl into which individual product pieces were dipped and rotated until all exposed surfaces had been wetted with the mixed culture. Product pieces were then placed on a sterile tray for 5 min to allow excess culture to drain off and were then placed on a conveyor belt leading into the radiant heat oven. With the use of the dip inoculation method, inoculation levels of ca. 1×10^9 to 3×10^9 CFU per product were typically achieved, as determined by recovery from inoculated but unheated control samples.

For the contact inoculation method, sponge-foam padding material (ca. 5 to 6 cm thick) was cut to the shape of a petri plate, autoclaved in foil-covered beakers, and used to pick up the mixed-strain inoculum lawn from inoculated petri plates after overnight incubation on agar plates with the use of a contact and twist motion. The inoculum was then contact inoculated onto the surface of the product with the same twist motion. The inoculated product was then placed on the conveyor leading into the radiant heat oven. As determined from nonheated control samples, the contact inoculation method also provided initial *L. monocytogenes* levels of 1×10^9 to 3×10^9 CFU per product sample.

Prepackage pasteurization with a radiant heat oven. A radiant heat oven (480 V, 30 A; Infrared Grill) was obtained from Unitherm Foodsystems (Bristow, Okla.) and installed in our pathogen processing pilot plant (Fig. 1A and 1B). The oven consisted of a stainless steel conveyor belt with heating elements positioned above and below it (Fig. 1). Heating coils had 12 in. (30.5 cm) of lateral clearance at the level of the conveyor belt and 8 in. (20.3 cm) of vertical clearance above the belt; separate bottom coils were positioned 5 in. (12.7 cm) below the belt. The coils themselves were spaced 2.5 to 3 in. (6.3 to 7.6 cm) apart. Inoculated product pieces were passed through the radiant heat oven (Fig. 1) for various treatment times at full power (no. 5 dial setting for ham and roast beef) or 80% power (no. 4 dial setting for turkey bologna). Products were processed for treatment times of 45 to 120 s depending on the resilience of the product and the throughput requirements of the product's processors; treatment times were adjusted by altering the speed of the belt. Product logs were placed lengthwise on the belt. Half rounds of roast beef were pasteurized both with the cut face facing the end of the oven and with the cut face facing to one side. After passage through the oven, product samples were placed into a sterile bag, chilled in an ice-water slurry, and rinsed with a chilled sterile diluent (50 ml of 0.1% buffered peptone water) to recover cells for microbial analysis (usually within 15 to 20 min); inoculated but unheated control samples were treated similarly. The same procedure was used for all meat samples.

Postpackage surface pasteurization. Postpackage surface pasteurization of fully cooked deli ham, roast beef, and turkey bologna was carried out as described previously with a 50-gal (189-liter) steam-injected temperature-controlled water bath *(7)*.

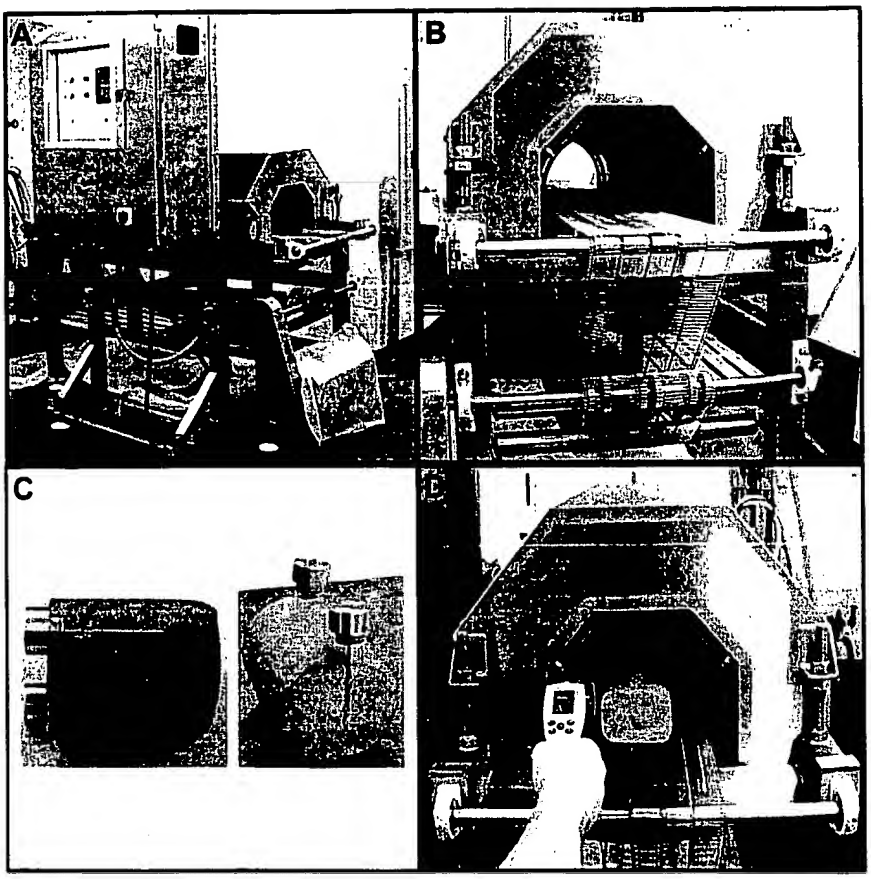

FIGURE 1. *The radiant heat oven used in this study. (A) Control box, conveyor belt, and radiant oven. (B) Internal view of heating coils. (C) Attachment of temperature-hardened DataTrace probes to turkey bologna product. (D) Raytek ST80 handheld infrared temperature monitor.*

For samples processed by postpackage pasteurization alone (roast beef), we used a 25-ml inoculum. Additional resuspension diluent was used after pasteurization to ensure the recovery of the remaining inoculum.

Combination pre- and postpackage surface pasteurization. We investigated a combination pasteurization process that included a short prepackage pasteurization treatment (for 45 or 60 s) followed quickly by vacuum packaging and postpackage pasteurization (for 45, 60, or 90 s) by submersion and subsequent microbial analysis as described previously *(7)*.

Product temperature measurement. Product temperatures were measured by several methods. Temperature-hardened DataTrace probes (Mesa Labs, Lakewood, Colo.) were placed at the tops, bottoms (offset to one side), sides, fronts, and backs of turkey bologna samples to determine the oven's temperature distribution on all sides of the product, which could not easily be determined by any other method (Fig. 1C). An infrared digital thermometer (Raynger Model ST80, Raytek, Santa Cruz, Calif.) that could provide the average, minimum, and maximum temperatures of the locations of eight infrared dots projected onto a product in a circular pattern was also used (Fig. 1D).

Microbiological analysis. For the recovery of the inoculum bacteria remaining after radiant heat and/or postpackage pasteurization, products were placed into large sterile bags, and 25 to 50 ml of buffered peptone water was added. The bags were then shaken and massaged for 5 min to resuspend surviving bacteria in the rinse buffer. Recovery of the rinse buffer was followed by appropriate serial dilutions and pour plating on TSA containing the antibiotics specified above. The plates were then incubated for 48 h at 30°C.

Experimental design. Except for one trial involving frozen-and-thawed roast beef that was carried out in duplicate, all trials were carried out in triplicate. Inoculated control samples and experimental samples were run in pairs for each processing condition within a replicate. Different replications were carried out on separate days with different lots of the same product and with pairs of samples from the same lot for each test condition. Standard deviations were obtained for multiple samples in the various replications. Treatment times were limited to those of practical application by the various participating processors.

RESULTS AND DISCUSSION

In this study, we examined prepackage surface pasteurization of RTE meats with the use of a radiant heat oven (Fig. 1A and 1B) alone and in combination with postpackage pasteurization *(7)* for the reduction of incidental *L. monocytogenes* contamination that could occur during postprocessing handling and packaging.

We examined the surface temperatures of a turkey bologna product with temperature-hardened probes. With the use of paired placements of probes (Fig. 1C) on turkey bologna (top–offset-bottom, left side–right side, front face–rear face) we were able to examine the temperatures on the various surfaces in order to test for major discrepancies. The largest discrepancy observed was that between the upper and lower product surface temperatures (Fig. 2A), which was a result of the "shielding" of the bottom of the product by the stainless steel mesh conveyor belt and was alleviated (Fig. 2B) by a design modification. In order to alleviate this condition, the manufacturer suggested making

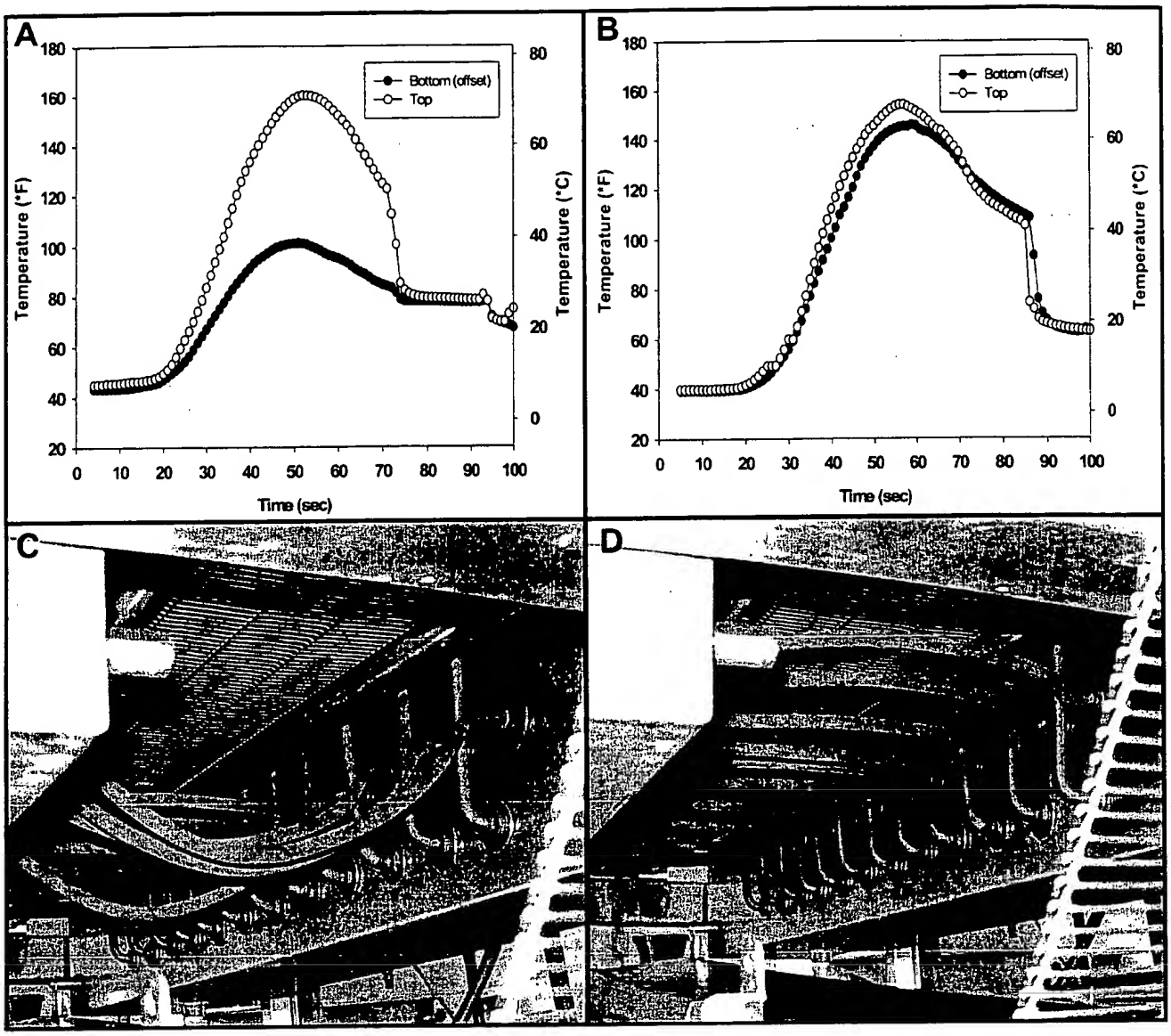

FIGURE 2. *Temperature profiles obtained from turkey bologna with temperature-hardened DataTrace probes placed on the top and on the bottom (offset from dead center) of the product in relation to the positioning of the underlying heating elements. Temperature profiles with bottom heating elements (A) turned down and away from the conveyor belt, (B) turned up toward the underside of the conveyor belt, (C) directed downward, and (D) directed upward toward the conveyor belt are shown. The radiant heat oven conditions included a 60-s treatment time, temperature setting no. 4, and an air temperature of 475°F (246°C).*

a rotational adjustment to the heating coils underlying the conveyor belt (Fig. 2C) to move the coils closer to the belt and the overlying product's bottom surface (Fig. 2D). This modification resulted in a noticeable and significant improvement in the top and bottom heating profiles compared with what had previously been observed. It should be noted that the "bottom" probes were placed "off center" and were not influenced by the temperature of the belt, which is nominally 95 to 99°F (35 to 37°C) upon its return to the oven entrance, since approximately 65 to 70% of the circuit of the circular belt is outside the oven; this is also the case for larger commercial systems.

Although we used metal-tipped probes to obtain surface measurements, we recognized that these probes could be susceptible to errors. If the probes are placed 1 to 2 mm too deep (along the surface), they may measure more subsurface temperature, and if placed too high, they may be influenced more by air temperature, and therefore extreme care was taken in their placement. Our intention was to determine whether gross temperature differences existed, because we expected that different products of different shapes and sizes would be positioned closer to or farther from the upper heating coils in practical use, and this would present a problem with any fixed-distance radiant oven. A handheld infrared thermometer that gave the average temperatures at the locations of eight infrared dots projected onto the surface of a product (Fig. 1D) was also used. At first, this infrared thermometer appeared to be a better means of obtaining accurate surface temperature measurements. However, temperature values would change as either conveyor belt or hand movement would change the positions of the dots and the exact points that were being mea-

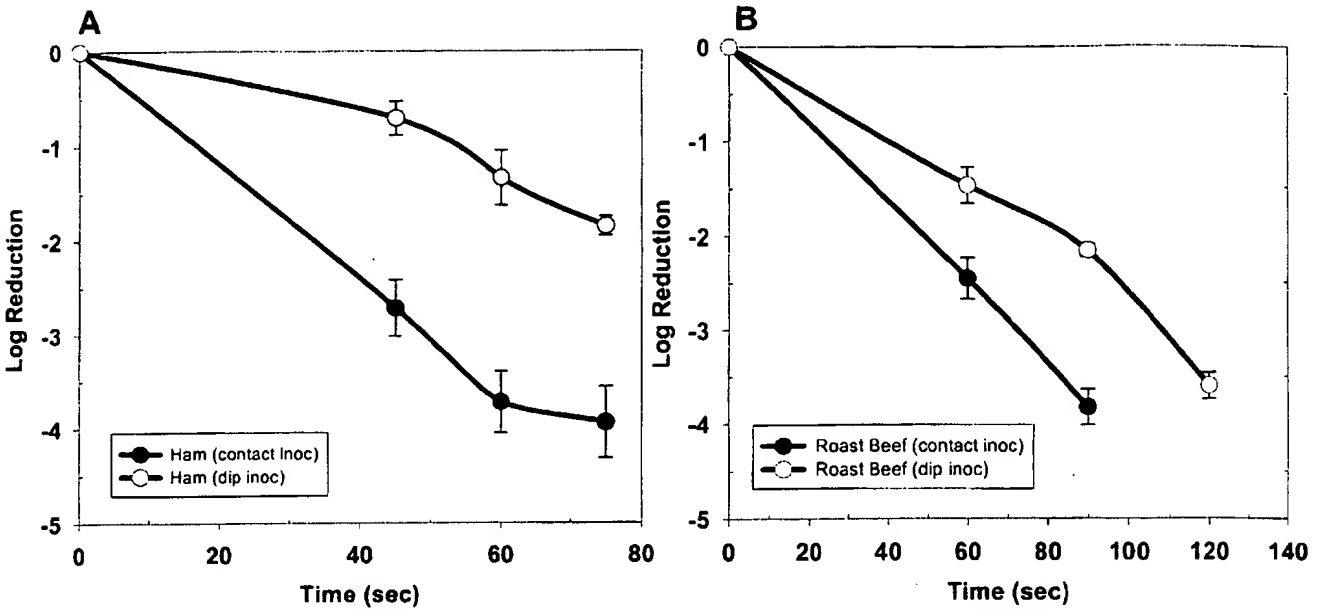

FIGURE 3. *Radiant heat surface pasteurization of (A) ham and (B) roast beef inoculated by the dip method or the contact method and processed at highest power setting for the time indicated. Each data point represents the mean for paired samples from triplicate replications. Error bars represent standard deviations of the mean.*

sured. It is conceivable that a mounted infrared temperature sensor-monitor could provide continuous monitoring of product as it exits the oven to provide a continuous real-time alert if targeted surface temperatures are not achieved (i.e., with the sensor-monitor pointing at the product, perhaps through a hole in the exit housing, as it exits the oven). With the handheld infrared monitor, we observed surface temperatures for ham in the ranges of 138 to 162°F (59 to 72°C; 30-s treatment time), 147 to 189°F (64 to 87°C; 45-s treatment time), 154 to 209°F (68 to 98°C; 60-s treatment time), and 165 to 215°F (74 to 102°C; 75-s treatment time). Some cut meat surfaces (turkey bologna, roast beef half rounds) showed somewhat lower temperatures than other surfaces, either because the cut flat side was offset from directly facing the heat source or because the cut sides also showed slight sweating (purge) during heating. Occasionally, surface temperatures as high as 250°F (121°C) would be observed, but temperatures would quickly decrease as the product moved.

As with postpackage pasteurization, care should be taken in developing microbial-reduction processing models based on surface temperatures without confirmatory inoculation studies. It is clear from various high surface temperature measurements we obtained that the accompanying microbial reduction was not in line with what would be expected on the basis of extrapolation from *D*-values (decimal reduction times) for the inoculated pathogens *(7)*. Unlike the heating of fully cooked products to a specific internal temperature so that the entire product from the center outward has reached at least the target temperature, brief surface heating may not necessarily penetrate all of the cuts, folds, and crevices that can be accessed by bacteria, and therefore single-point, or even multipoint, temperature readings for the outermost surface may be of limited practical application.

In previous studies of postpackage pasteurization, a fixed amount of inoculum was added to each of the products in vacuum-packaging bags before the bags were vacuum sealed *(7)*. This method of inoculation had to be modified for use with surface inoculation of a nonpackaged product, and therefore we examined both a dip inoculation method and a contact inoculation method and contemplated the practical difference between the two methods after they had been used in several pasteurization trials. RTE deli ham and roast beef half rounds inoculated by both methods were surface pasteurized (Fig. 3). The results obtained indicate that *L. monocytogenes* reductions for the contact inoculation method were 1 to 2 log cycles larger than those for the extreme dip inoculation method. During the radiant heat surface pasteurization of hams inoculated with *L. monocytogenes* and processed for 45 to 75 s, we obtained 0.75- to 1.85-log reductions when the dip method was used and 2.7- to 3.9-log reductions when the contact inoculation method was used (Fig. 3A). Similarly, with roast beef we achieved 1.5- to 2.2-log reductions for the dip inoculation method and 2.5- to 3.8-log reductions for the contact inoculation method when samples were processed for 60 to 90 s (Fig. 3B). The differences between the two inoculation methods are reasonably assumed to be due to the aggressive infiltration of small cracks, crevices, and folds, which protects some of the bacteria from the full heating regimen, when the dip method is used.

Our results indicate that radiant heat pasteurization can reduce incidental contamination that may be acquired upstream during postprocessing handling. We propose that this process would be most effective just prior to final packaging, a stage for which no such microbial interventions currently exist. However, there could still be concerns about contamination during the final packaging, although such contamination would be minimized if the product were

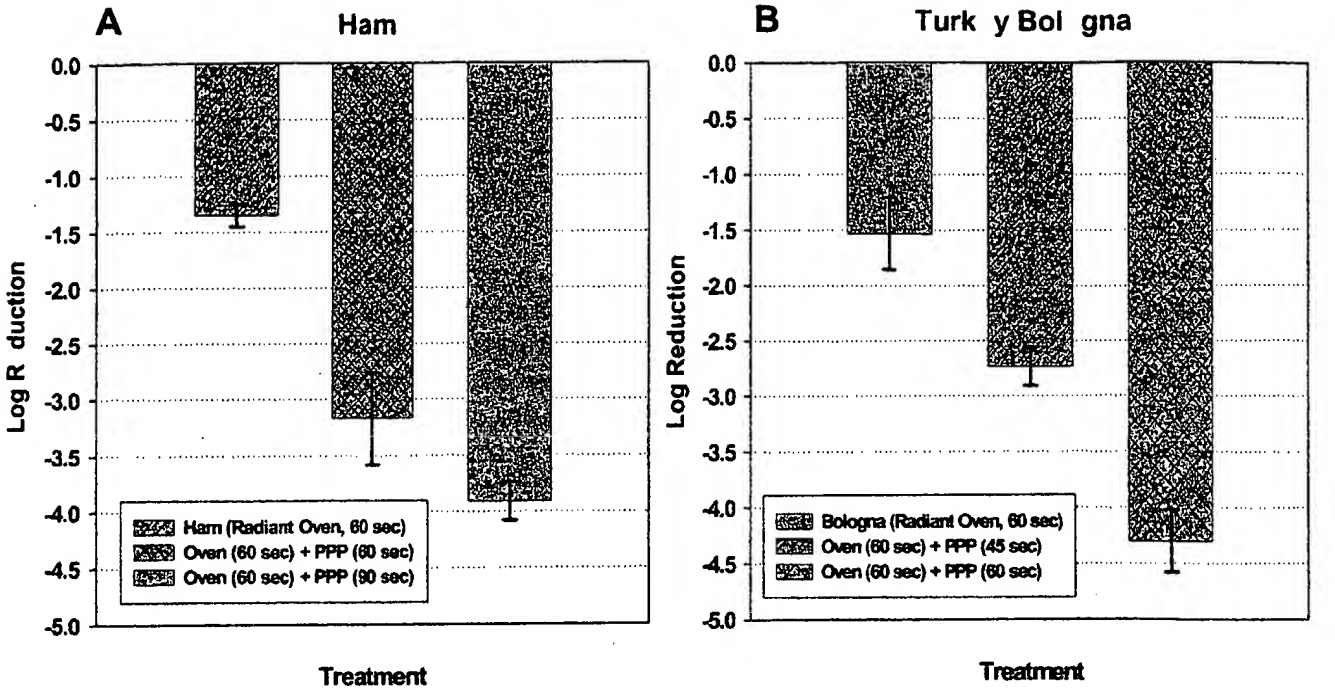

FIGURE 4. *Radiant heat prepackage surface pasteurization of (A) formed ham and (B) turkey bologna alone and in combination with postpackage pasteurization. Prepackage pasteurization was performed at temperature setting no. 5 (the highest setting) for ham (for an air temperature of 750°F [399°C]) and at temperature setting no. 4 for bologna (475°F [246°C]) with a 60-s treatment time for both products. Postpackage pasteurization (PPP) was applied for 60 or 90 s for ham and for 45 or 60 s for turkey bologna at 200°F (93.3°C). Products were inoculated by the dip method.*

packaged immediately while still hot. With this in mind, we further examined a combined pre- and postpackage pasteurization step that would provide the benefit of direct surface heating of prepackage pasteurization along with the added benefit of further pasteurization after the final packaging while the surface is still warm (at which point no further exposure to contamination due to handling would occur). For formed ham and turkey bologna, we obtained 1.35- and 1.53-log reductions of *L. monocytogenes*, respectively, when a 60-s radiant heat surface pasteurization step was used with product inoculated by dip method, our most aggressive inoculation method (Fig. 4). When prepackage pasteurization of the ham was followed by 60- or 90-s postpackage pasteurization at 200°F (93.3°C), we obtained overall 3.17- and 3.91-log reductions of *L. monocytogenes*, respectively (Fig. 4A). When prepackage pasteurization of the turkey bologna was followed by 45- or 60-s submersed water postpackage pasteurization, we obtained overall 2.73- and 4.3-log reductions of *L. monocytogenes*, respectively (Fig. 4B).

The results of our examination of both the dip and the contact inoculation methods suggest that the contact inoculation method is more typical of the manner in which incidental contamination is acquired in plants and that this method is more practical for the surface inoculation of large nonpackaged deli meat products. It is important to note that the contact inoculation method does not undercut the safety of process evaluation, since the typical sponge-delivered contact inoculum for our deli products resulted in *L. monocytogenes* levels of ca. 10^9 CFU per product piece tested, and all products were inoculated in this manner on several sides. There is no conceivable way that fully cooked product could acquire such high levels of *Listeria* through contact unless growth-permissive conditions were involved.

In an additional roast beef study involving only contact inoculation, we examined the effect of radiant heat surface pasteurization on whole and half rounds of roast beef positioned in the oven with the cut side facing either forward or to the side, and we compared frozen-and-thawed roast beef product processed by radiant heat pasteurization alone with that processed by radiant heat pasteurization in combination with postpackage pasteurization (Fig. 5). Radiant heat pasteurization of both whole and half rounds of fresh refrigerated roast beef (regardless of position) as well as whole logs of corned beef resulted in similar *L. monocytogenes* reduction levels (2.15 to 2.45 log cycles) (Fig. 5A). However, radiant heat pasteurization of frozen-and-thawed roast beef resulted in lower reduction levels (1.5 log cycles), presumably owing to the destruction of meat cells, leading to an increase in the "juiciness" of the roast beef after thawing (Fig. 5B). When frozen-and-thawed roast beef was processed via short-term postpackage pasteurization (for 60 and 90 s), freezing and thawing together with the short processing time was also found to result in low *L. monocytogenes* reduction levels (Fig. 5B). However, whether roast beef was fresh, or frozen and thawed, the use of the combination of 60 s of radiant heat pasteurization followed by 60 or 90 s of postpackage pasteurization (200°F) resulted in reduction levels of >3 log cycles (Fig. 5A and 5B), which would have required 10 min to achieve with postpackage pasteurization alone. It should be noted that for fresh roast beef, the combination of 60 s of radiant heat

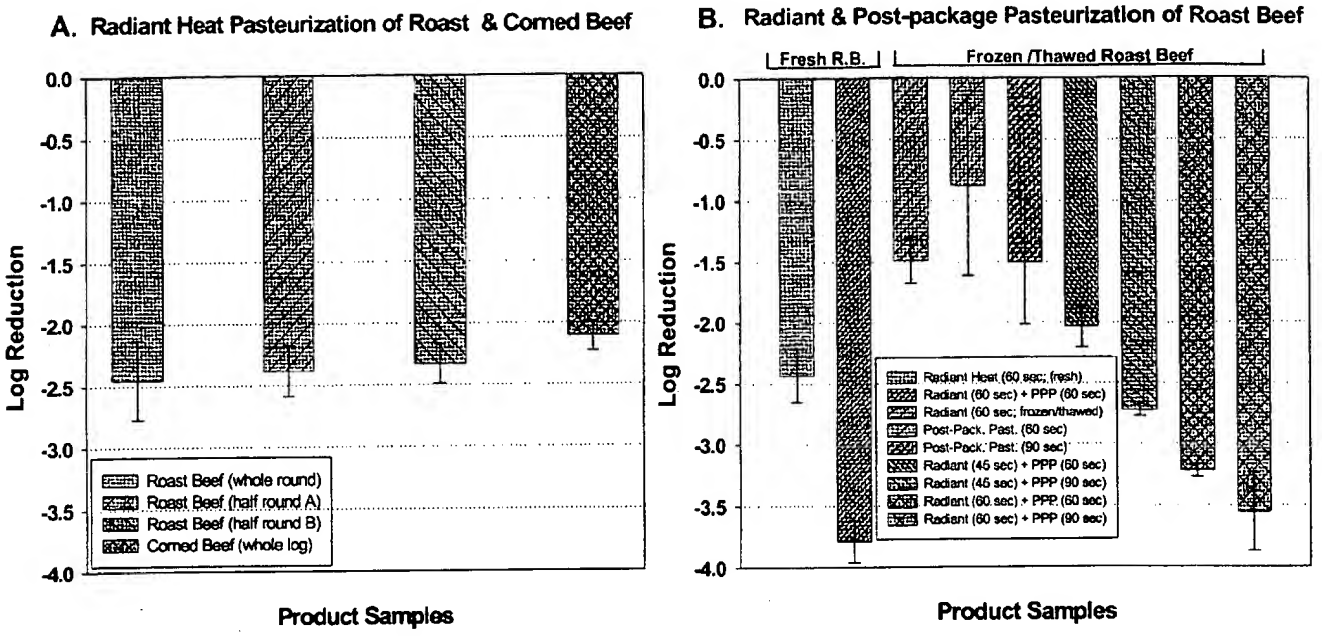

FIGURE 5. *Radiant heat prepackage pasteurization of roast beef alone and in combination with postpackage pasteurization. (A) Radiant heat surface pasteurization of roast beef top rounds (whole round, 13 to 16 lb), half rounds with the cut sides facing the tunnel exit ("A," 6.5 to 8 lb), half rounds with the cut sides facing to the side ("B," 6.5 to 8 lb), and corned beef logs (whole, 25 to 27 lb). (B) Radiant heat surface pasteurization alone, submerged water postpackage pasteurization (PPP) alone, and a combination of pre- and postpackage surface pasteurization of roast beef half rounds. Treatments are as indicated. All of panel A and the first two bars of panel B represent fresh refrigerated product; the remainder of panel B represents product that was frozen and then thawed for testing. All samples were inoculated by the contact inoculation method.*

pasteurization and 60 s of postpackage pasteurization resulted in larger reductions than a slightly longer process (60 s of radiant heat pasteurization and 90 s of postpackage pasteurization) did for frozen-and-thawed roast beef (Fig. 5B). The reduction in the time required for the postpackage pasteurization phase of the combination process (60 or 90 s) provided the additional benefit of generating little or no purge compared with what we have observed in trials involving longer postpackage pasteurization times (4, 6, 8, and 10 min) *(7)*. These data demonstrate the effectiveness of a short-duration combined process that provides additional processing after final packaging with no further handling of the product in significantly reducing pathogen levels. However, the heat-treated product may need to be chilled prior to boxing, since the surface quarter inch has been heated.

The results of the present study indicate that radiant heat prepackage surface pasteurization, postpackage surface pasteurization *(7)*, or a combination of the two processes can alleviate potential *Listeria* contamination on RTE deli meat surfaces with minimal effects on product quality. The benefits of such a process should be considered with respect to the potential for a product's acquisition of contamination in plant environments in which RTE products are manufactured and packaged and in comparison with those of preexisting processing lines that do not include additional intervention steps. The potential savings of such a process must be measured in view of recent large recalls (and, worse, illnesses and deaths) that have been attributed to the manufacture and distribution of contaminated products. The data provided herein demonstrate that new processing strategies and microbial interventions that can provide safe products for the benefit of consumers and processors alike are currently available.

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COMPLIANCE GUIDELINES TO CONTROL LISTERIA MONOCYTOGENES IN POST-LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY PRODUCTS

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EXHIBIT 6

A. Requirements of the Final Rule

Listeria monocytogenes is a pathogen that is widely distributed in the environment such as plant, soil, animal, water, dirt, dust, and silage. Because L. monocytogenes can be found in slaughter animals and in raw meat and poultry and other ingredients, it can be continuously introduced in the processing environment. The pathogen can cross-contaminate food contact surfaces, equipment, floors, drains, standing water and employees. In addition, the pathogen can grow in damp environments and can establish a niche and form biofilms in the processing environment that is difficult to eliminate during cleaning and sanitizing. Other characteristics of L. monocytogenes that makes it a formidable pathogen to control are its heat and salt tolerance and its ability to grow at refrigeration temperatures.

The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products eliminate the pathogen, however products can be re-contaminated by exposure after the lethality treatment during peeling, slicing, repackaging, and other procedures. Several foodborne illnesses resulting in hospitalization, miscarriage and death have been linked to the consumption of deli meats and hotdogs containing L. monocytogenes. The cause of L. monocytogenes contamination in these outbreaks was traced to post-lethality exposure and contamination by the pathogen. Hot dogs and deli meats are examples of RTE meat and poultry products that receive a lethality treatment to eliminate pathogens, and are subsequently exposed to the environment during peeling, slicing, and repackaging operations. If L. monocytogenes is present in the equipment used for peeling, slicing or repackaging, the pathogen can be transferred to the product upon contact. Since RTE products are consumed without further cooking for safety, there is a possibility of the occurrence of foodborne illness.

RTE meat and poultry processing plants must include control programs for Listeria monocytogenes in their HACCP plan, Sanitation SOP or prerequisite programs to prevent its growth and proliferation in the plant environment and equipment, and cross-contamination of RTE products. The final rule for the control of Listeria monocytogenes include three alternative methods that establishments can use in the processing of RTE meat and poultry products during post-lethality exposure. These alternatives are based on different ways of controlling L. monocytogenes used in the processing of RTE products that are exposed to the environment after the lethality treatment. The risk for contamination by the pathogen increases from alternative 1 to 3, based on the control methods used by the establishment. Alternative 1 requires an establishment to apply a post-lethality treatment and an antimicrobial agent or process to control L. monocytogenes. Alternative 2 requires an establishment to apply either a post-lethality treatment or an antimicrobial agent or process. In alternative 3, the establishment does not apply any post-lethality treatment or antimicrobial agent or process, so it is required to have a sanitation program that includes testing food contact surfaces and holding product when tests turn out positive. An establishment must identify to which alternative their RTE product falls into based on its control program for L. monocytogenes. An establishment must apply the control methods required for the specific alternative in its

processing so it can qualify for the alternative. Each alternative has requirements that the establishment must comply to.

The compliance guidelines aim to help the establishment in its use of control methods for L. monocytogenes. Its purpose is to show establishments what the control methods used singly or in combination can achieve to prevent or eliminate L. monocytogenes contamination in the product during post-lethality exposure. Establishments can use the guidelines to determine control methods that are best suited to their processing. Some establishments may have instituted methods which they have verified to be effective in controlling the pathogen and may not need to change their methods to follow these guidelines. However, FSIS will make a determination on the effectiveness of the controls and establishment verification testing when deciding how FSIS will conduct verification in the establishment. These guidelines will be updated as necessary to include validated and other effective procedures as they become available.

Alternative 1

Alternative 1 requires the use of post-lethality treatment (which maybe an antimicrobial agent) to reduce or eliminate L. monocytogenes and an antimicrobial agent or process to suppress or limit the growth of the pathogen. For RTE products that are cooked and then removed from their cooking bag and sliced, diced or repackaged, there is a risk of cross contamination from the equipment, conveyor belts and the environment. These products need to be aseptically processed and then repackaged under strict sanitary conditions to prevent contamination from L. monocytogenes. Post lethality treatments such as steam pasteurization, hot water pasteurization, radiant heating and high pressure processing have been developed to prevent or eliminate post-processing contamination by L. monocytogenes. RTE products where post-lethality treatments were shown by studies to be effective in reducing the level of L. monocytogenes are whole or formed ham, whole and split roast beef, turkey ham, chicken breast fillets and strips, and sliced ham, sliced turkey, and sliced roast beef.

Examples of antimicrobial agents shown to inhibit listerial growth are lactates, acetates or diacetates added in the formulation and the use of growth inhibitors in the immediate packaging material. Some growth inhibitor packaging and some levels and combinations of antimicrobial agents were shown by research studies to reduce the levels of L. monocytogenes. RTE products where studies on antimicrobial agents were shown to be effective in the control L. monocytogenes are hot dogs, bologna, cotto salami, and bratwurst.

An establishment whose product or process falls in Alternative 1 must have the post-lethality treatment that reduces or eliminates the pathogen in its HACCP plan. The post-lethality treatment must be validated according to § 417.4 as being effective in reducing or eliminating L. monocytogenes and the validation should specify the log reduction achieved by the post-lethality treatment and antimicrobial agents. The effectiveness of the post-lethality treatments and antimicrobial agents must be verified and have the verification results available to FSIS personnel upon request.

The antimicrobial agent or process that limits or suppresses L. monocytogenes must be included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishments must have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of L. monocytogenes. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with § 417.4. If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 416.14. If the control measures for L. monocytogenes are contained in a prerequisite program other than a Sanitation SOP, the program must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate.

Post-lethality treatments can be applied as a pre-packaging treatment, e.g. radiant heating, or as post-packaging treatments, e.g., hot water pasteurization, steam pasteurization, and high pressure processing. Some of the studies on post-lethality treatments are reviewed in section B. Establishments should refer to the details of the studies if they want to use the intervention method in their processing. The guidelines will be updated to include studies or other methods as they become available. Studies on post-lethality treatments showed reductions of inoculated L. monocytogenes from 1 to 7 $\log_{10}$ CFU/g depending on the product type, and duration, temperature and pressure of treatment. Higher log reductions were obtained when both pre-packaging and post-packaging surface pasteurizations were applied, and when post-lethality pasteurization was combined with the use of antimicrobial agents.

An establishment can use available published research studies as reference for their validation provided it uses the product type or size, the type of equipment, time, temperature, pressure and other variables used in the study in order to result in the same level of reduction of L. monocytogenes. An establishment that uses products, treatments or variables other than those used in the studies must perform its own validation studies to determine the effective reduction of L. monocytogenes as a result of the post-lethality treatment or antimicrobial agent applied to the products. Some of the published studies use different products and report a range of levels of reduction of L. monocytogenes. In this case, the establishment must validate the use of the post-lethality treatment or antimicrobial agent for their specific products. The establishment must specify the level of reduction achieved by the post-lethality treatment or antimicrobial agent applied in their validation. Aside from validation of the post-lethality treatment and antimicrobial agent, the establishment must verify its effectiveness by testing for L. monocytogenes.

Antimicrobial agents can be added to the product formulation, to the finished product or to the packaging material to inhibit growth of L. monocytogenes in the post-lethality exposed product during its refrigerated shelf life. Studies on antimicrobials added to the packaging material or active packaging showed a 1-2 $\log_{10}$ CFU/g reduction of L. monocytogenes during the refrigerated shelf life of the products. Lactates, acetates and diacetates are some antimicrobials added to the formulation of RTE meat and poultry

products. Based on published studies, growth reduction or inhibition achieved by adding these antimicrobials to product formulation depends on a variety of factors. Depending on the amount of antimicrobials and other growth inhibitors added to the product formulation and other ingredients in the product, growth inhibition of L. monocytogenes was shown to range from 30 days to 120 days at refrigerated temperatures. Some published studies on antimicrobials are reviewed in section C. Establishments should refer to the details of the studies if they want to use the intervention method in their processing.

An antimicrobial process that controls the growth of L. monocytogenes in the post-lethality environment is a lethality process that renders a RTE product shelf stable. Shelf stable products are formulated with salt, nitrites and other additives, and processed to achieve a water activity, pH and moisture-protein ratio that will reduce the level of L. monocytogenes and other pathogens during processing. In addition, the lethality treatment exerts a continuing bactericidal and bacteriostatic effect and does not support the growth of L. monocytogenes and other pathogens during the shelf life of the product at ambient temperatures. In this case, the antimicrobial process could serve as a both a post-lethality treatment and growth inhibitor. The establishment should have documentation on file to demonstrate the effectiveness of the lethality treatment through the shelf life of the product. Examples of shelf stable RTE products are country cured ham, pepperoni, salami, and jerky.

Another antimicrobial process that controls the growth of L. monocytogenes in the post-lethality environment is freezing of RTE products. Freezing prevents the growth of any microorganisms in the product because their metabolic activities are arrested, but depending on the method and length of freezing and other factors, some microbial kill can also result. Like other microorganisms, L. monocytogenes is resistant to freezing. Once the product is thawed, metabolic activities of microorganisms may resume, depending on whether the microorganisms are killed, injured, or not affected at all. Therefore this antimicrobial process is only effective while the product is frozen. Labels of RTE frozen products contain cooking instructions for the frozen product and for thawed and refrigerated product, and instructions for thawing at refrigerated temperatures. Examples of frozen RTE products are fully cooked frozen chicken nuggets, fully cooked frozen chicken breast patties or fully cooked frozen dinners.

The establishment can include the antimicrobial treatment that limits or suppresses L. monocytogenes in the HACCP plan, or Sanitation SOP or prerequisite program. However, the establishment must show the effectiveness of the antimicrobials in suppressing or limiting L. monocytogenes in these programs. An establishment can use published studies as reference for its validation as long as it uses the same treatment variables as those used in the study. These variables include among others, specific antimicrobial agents, concentration, time and temperature of effectiveness and others. Use of antimicrobial singly or in combination, with different concentration and other variables, and for products not used in the studies must be validated or tested for their effectiveness. This must be validated for the HACCP plan, or documented in the Sanitation SOP or other prerequisite programs. The establishment must verify that the

antimicrobial program is effective by testing product for L. monocytogenes and must verify that it does not cause the hazard analysis or the HACCP plan to be inadequate.

An establishment with products in Alternative 1 must maintain sanitation in the post-lethality processing environment in accordance with part 416. The establishment must make the verification results that demonstrate the effectiveness of its controls, whether from carrying out its HACCP plan, or its Sanitation SOP, or other prerequisite program, available upon request to FSIS inspection personnel.

Establishments have been using prerequisite programs before in their processing operations, and the Agency has recently accepted the use of prerequisite programs as an option in another policy. However, giving the establishment the option to include the antimicrobial agent or process in a prerequisite program in this rule is the first time prerequisite programs are recognized in codified regulations.

An establishment with products in Alternative 1 must have a post-lethality treatment that effectively reduce or eliminate L. monocytogenes, and an antimicrobial agent or process that suppresses any growth of the pathogen and extend the effect of the post-lethality treatment during the shelf life of the product. The Agency considers these treatments to be effective in controlling the pathogen to result in a safe RTE product. If an establishment has an effective Sanitation SOP, any contamination by L. monocytogenes would be very small, so the post-lethality treatment and the antimicrobial will be able to reduce or eliminate this contamination. If there is gross contamination, the effectiveness of the treatments may be reduced or negated. Therefore the Agency is relying on the establishment's Sanitation SOP to prevent contamination with L. monocytogenes, and the post-lethality treatment and antimicrobials to further reduce or eliminate the pathogen.

Because of this combination of controls, the Agency is not requiring establishments to have a testing program for food contact surfaces. However, the establishments can test food contact surfaces for L. monocytogenes, or its indicator organisms, Listeria spp. or Listeria-like organisms, to verify that their Sanitation SOP is effective. L. monocytogenes belongs to the Listeria group or genus of microorganisms, therefore a positive test for Listeria spp. or Listeria-like organisms would indicate the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that L. monocytogenes is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator tests for L. monocytogenes. Results from these tests do not indicate the presence or absence of the pathogen. Guidelines on sanitation procedures and food contact surface testing for L. monocytogenes or its indicator organisms, Listeria spp. or Listeria-like organisms, are found in section D.

Alternative 2

An establishment that identifies its products in Alternative 2 must apply either a post lethality treatment or an antimicrobial agent or process that controls the growth of L. monocytogenes. The establishment must have the post-lethality treatment in its HACCP plan and must be validated according to § 417.4 as being effective in reducing or

eliminating L. monocytogenes and should specify the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment must be verified by testing for L. monocytogenes and have the verification results available to FSIS personnel upon request. If an establishment has a product identified in Alternative 2 and uses a post lethality treatment to control L. monocytogenes in its product, it is not required to test food contact surfaces in the post-lethality environment. However, it can test food contact surfaces for L. monocytogenes, or its indicator organisms (Listeria spp. or Listeria-like organisms), or it could be subject to frequent verification testing by FSIS if it does not.

An establishment in Alternative 2 that only uses an antimicrobial agent or process to control L. monocytogenes in its product must have the agent or process included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishments should have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of L. monocytogenes. The establishment should document the log levels of the pathogen that the antimicrobial agent or process can suppress and the length of time in days that the antimicrobial is effective. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with § 417.4.

If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 416.14. If the control measures for L. monocytogenes are contained in a prerequisite program other than a Sanitation SOP, the program must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment should document its antimicrobial agent or process, its implementation and its verification results sufficiently in order to show that the HACCP plan is adequate in controlling the pathogen. The establishment must verify that the antimicrobials are effective by testing for L. monocytogenes and have the verification results whether from carrying out its HACCP plan, or its Sanitation SOP, or other prerequisite program, available upon request to FSIS inspection personnel.

If an establishment's product is in Alternative 2 and uses an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes in its product, it should maintain sanitation in the post-lethality environment in accordance with part 416. The sanitation program must include testing for food contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of L. monocytogenes or its indicator organisms (Listeria spp. or Listeria-like organisms). Studies on antimicrobials showed growth inhibition of L. monocytogenes if present at low levels of contamination during the shelf life of the RTE product. Antimicrobials were not shown to be effective at higher levels of contamination, so an effective sanitation program, which includes verification testing for food contact surfaces must be implemented at the same time that antimicrobials are used.

The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of l. monocytogenes or its indicator organisms. It must include the frequency of testing and identify the size and location of the sample sites to be sampled. It should include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes or its indicator organisms is maintained. In addition, the establishment must identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for L. monocytogenes or its indicator organisms. The product will be subject to FSIS verification testing, because the establishment is not relying on a post-lethality treatment to eliminate L. monocytogenes.

Alternative 3

A post-lethality exposed product that does not use a post-lethality treatment or an antimicrobial agent or process to control the growth of L. monocytogenes fall under Alternative 3. An establishment producing this product must control the pathogen in its post-lethality processing environment through the use of sanitation control measures. Because the establishment is not relying upon a post-lethality treatment or an antimicrobial agent or process to control L. monocytogenes, the product will be subject to frequent FSIS verification testing. Examples of products in this alternative are fully cooked meat and poultry that are packaged and refrigerated such as hotdogs, deli meats, chicken nuggets, or chicken patties.

For this alternative, the establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416. The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of L. monocytogenes or its indicator organisms. The testing program should include the frequency of testing, identify the size and location of the sample sites and include an explanation of why the testing frequency is sufficient to ensure that effective control of L. monocytogenes or its indicator organisms is maintained. In addition, the establishment should identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for L. monocytogenes or its indicator organisms on a food contact surface.

Moreover, an establishment that produces a deli product or a hotdog product must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for L. monocytogenes or its indicator organisms on a food contact surface in the post-lethality processing environment are effective. The corrective action must indicate steps that the establishment will take to clean and sanitize the suspected food contact surfaces to eliminate the contamination. The verification of the effectiveness of the corrective action can be shown by follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and other additional tests in the surrounding food contact surface area as necessary to ensure the effectiveness of the corrective actions. During this follow-up testing, if the establishment obtains a second positive test for L. monocytogenes or an indicator organism, the establishment must hold lots of product that may have become

contaminated by contact with the food contact surface until the establishment corrects the sanitation problem indicated by the test result.

Further, in order to be able to release into commerce the lots of product that may have become contaminated with L. monocytogenes from the food contact surface, the establishment must sample and test the lots for L. monocytogenes using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with L. monocytogenes. If the product tests positive for L. monocytogenes, the product is considered adulterated and must be withheld from commerce. The establishment may destroy the held product , or rework the held product using a process that is destructive of L. monocytogenes. The establishment must document the results of the testing and the disposition of the product. An example of a hold-and test scenario can be found in section E-VIII.

An establishment with products in Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment with products in Alternative 1 or 2. This is because the products in Alternatives 1 and 2 are formulated and/or processed to reduce or eliminate L. monocytogenes or limit its growth in the RTE product and present a lower risk than products in Alternative 3 that do not have these interventions. Likewise, an establishment in Alternative 3 that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for L. monocytogenes contamination by the risk assessment.

Labeling

Antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products are required to be included in the ingredients statement of the product label. In addition, establishments that use a post-lethality treatment or an antimicrobial validated to effectively eliminate or reduce L. monocytogenes, or suppress or limit its growth in the product can make claims or special statements on the labels of their products regarding the presence and purpose of use of the substances. The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary, and may be of value to consumers especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims. An example of a statement that can be made is: "Potassium lactate added to prevent the growth of L. monocytogenes." All labeling claims and label changes to add such claims must be submitted for evaluation and approval to the FSIS Labeling and Consumer Protection Staff.

Estimates of Annual Production Volume

An establishment that produces post-lethality exposed RTE products shall provide FSIS with estimates of annual production volume and related information (such as the establishment's testing program) for the types of meat and poultry products processed

under Alternatives 1, 2, or 3. The establishment needs to provide the information at least annually, or more often, as determined by the Administrator. The Agency regards production volume as a more important risk factor than establishment size and therefore needs these data so that it can target its resources on higher volume operations in its verification program. FSIS will develop sampling frequencies for the establishments and the products based on these data. The Agency will make the sampling frequency available to the establishments so that they will have an indication of how the risk of L. monocytogenes is tied to verification sampling.

The form by which to collect the data will be available to establishments in paper or electronic formats. An electronic form for this purpose will be available to the establishments at all times after the rule becomes effective.

B. Studies on Post-lethality Treatments

(Mention of trade marks or commercial names does not constitute endorsement by USDA)

I. Steam Pasteurization and Hot Water Pasteurization

Post processing contamination of RTE meat and poultry is mostly confined to the surface. Pasteurization by steam and hot water acts on the surface microbial contaminants by the action of heat. Studies on surface pasteurization using steam or hot water were shown to be effective in reducing this contamination.

Studies by Murphy et al. (2003a) showed that post-cook hot water pasteurization and steam pasteurization resulted in a 7 $\log_{10}$ reduction of L. monocytogenes in inoculated vacuum packaged fully cooked sliced chicken. The reduction was effective when single – packaged breast fillets, 227 g- package strips and 454 g-packaged strips were heat treated at 90 C in a continuous steam cooker or hot water cooker for 5, 25 and 35 minutes respectively. These investigators developed a model called ThermoPro that could predict the thermal lethality of pathogens in fully cooked meat and poultry products during post-cook in-package pasteurization (Murphy et al., 2001, 2003b, 2003c). The model was developed using L. innocua and verified for L. monocytogenes.

II. Pre-Package Pasteurization and Post-Package Surface Pasteurization

Muriana et. al., (2002) used a stainless steel water bath (similar to the Unitherm commercial Aquaflow food processor) to submerge cooked RTE deli-style whole or formed turkey, ham and roast beef, removed from their package, inoculated with L. monocytogenes and vacuum packaged. Results show a 2-4 log decrease in the levels of L. monocyogenes in inoculated products post-cooked at 195-205 F for 2-10 min.

Pre-package surface pasteurization treatment of the fully cooked meat removed from their packaging wrap and inoculated with L. monocytogenes resulted in a 1.25 to 3.5 log reduction with a treatment time of 60-120 s at 475 to 750 F air temperature (Gande and Muriana, 2003). Surface pasteurization was applied on cooked whole and split roast beef,

whole corned beef, and whole and formed ham using a radiant oven ("Infrared Grill", Unitherm FoodSystems). Pre-package pasteurization (60 sec) combined with post-package submerged water pasteurization using formed ham (60 or 90 sec), turkey bologna (45 or 60 sec), and roast beef (60 or 90 sec), resulted in a 3.2 to 3.9 log reduction for ham, 2.7-4.3 log reduction for bologna, or a 2.0-3.75 log reduction for roast beef. The level of reduction varied depending on the method of inoculation, type of product used, treatment temperature, and residence time.

III. High Hydrostatic Pressure Processing

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating L. monocytogenes in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions. Results show that an inoculum of about 10^4 L. monocytogenes cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of L. monocytogenes after 61 days of storage at 34° F. There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.

C. Studies On The Use of Antimicrobial Agents

I. Addition of Lactates, Acetates, Diacetates to Meat Formulations

Studies have shown that lactic acid and acetic acid have significant antimicrobial activity in broth and food systems. Sodium and potassium salts of these acids, when added to processed meat formulation are also known to potentially inhibit pathogenic bacteria especially L. monocytogenes. These antimicrobials inhibit growth of pathogens by inhibiting their metabolic activities. Interest in these antimicrobials is in the growth inhibition of L. monocytogenes in post lethality exposed RTE meat and poultry products.

FSIS recently increased the permissible levels of sodium acetate as a flavor enhancer in meat and poultry products, and of sodium diacetate as a flavor enhancer and as an inhibitor of pathogen growth to 0.25 %(65 FR 3121-3123/2000). The rule also permitted the use of sodium lactate and potassium lactate in meat and poultry products at 3 %, corresponding to a 4.8 % of the 60 % commercial product (except for infant formulas and infant food) for the purposes of inhibiting the growth of certain pathogens. The addition of antimicrobials in the formulation must be included in the ingredient statement of the label. Several studies used these antimicrobials to show their ability to inhibit growth of L. monocytogenes in different meat formulations.

Seman et al., (2002) developed a mathematical model capable of predicting the growth or stasis of L. monocytogenes in commercial cured meat products using a response surface method. The model can be used by manufacturers in the determination of the appropriate amounts of potassium lactate and sodium diacetate to be added to cured meat products that are organoleptically sensible and will not support the growth of L. monocytogenes. Thirty products were formulated by using a variety of raw material sources such as pork trimmings, trimmed turkey breast halves and four-muscle ham. Varying amounts of potassium lactate and sodium diacetate were added to the meat formulation and the meats were processed into different products. After chilling, the products were stripped of their casings, sliced into 25-g slices, placed into pouches, and inoculated with L. monocytogenes by applying to the surface of 100g of cured meat (four slices).

The results show that increasing amounts of potassium lactate syrup and sodium acetate decreased the growth rate of L. monocytogenes, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. The investigators provided final regression equation predicting the growth of L. monocytogenes in cured RTE meat products stored at 4° C. The investigators used predictive model performance factors and a simple linear regression analysis to evaluate the model generated in this study. They verified the accuracy of the model by comparing with actual L. monocytogenes growth data from independent challenge study conducted with for four different commercial RTE meat products using similar storage conditions. Performance factors calculated and evaluated for control products (those not containing potassium lactate and sodium diacetate) indicated that on the average, the predicted growth of L. monocytogenes exceeded those of the observed values by about 24 %.

This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of L. monocytogenes. The calculations would also require knowledge of the finished product sodium chloride and moisture contents. The investigators advised that this validated model is specific to the products designed for the study and the L. monocytogenes strains used. Testing of this model in other environments and with other Listeria spp., and to formulations that are outside the model's limits may result in different maximum growth rates. This study was used as the basis for the Opti.Form Listeria Control Model.

The Opti.Form Listeria Control Model (PURAC) is a unique tool to calculate the levels of lactate and diacetate required to retard the growth of Listeria monocytogenes in cured meat and poultry products. The model is based on the study detailed in the paper by Seman et al, 2002, above. The model, which is available on CD-Rom includes:

- instructions on how to use the model
- explanation on the development of the model
- information on the anti-microbial effect of lactate and diacetate
- lactates and diacetates and use of these products
- regulations and labeling
- literature references

To receive a free copy of the model on CD-Rom, call: 888-899 8229, E-mail pam@purac.com

Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on L. monocytogenes populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 10^3 to 10^4 CFU /cm^2 of L. monocytogenes after peeling and before vacuum packaging. Samples were stored at 4° C for up to 120 days and sampled for testing on assigned days. Results are as follows:

ANTIMICROBIAL	LEVEL (%)	L. MONOCYTOGENES GROWTH INHIBITION
Sodium lactate	3	70 days no pathogen growth
Sodium diacetate	0.25	50 days no pathogen growth
Sodium acetate	0.25, 0.50	20 days no pathogen growth
Sodium lactate	6	120 days no growth and reduced pathogen growth
Sodium diacetate	0.5	120 days no growth and reduced pathogen growth
Control	0.0	Increased to 6 logs in 20 days

No pathogen growth refers to no increase in the number of inoculated L.monocytogenes cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated L. monocytogenes cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Antimicrobials were found to have no effect on pH except for sodium diacetate at 0.5 % which reduced the initial pH. Using the formulations and conditions in the study, establishments can add 3 % sodium lactate in the frankfurter formulation and obtain no growth of L. monocytogenes up to 70 days at refrigerated storage of 4° C. If the lethality treatment is adequate to eliminate L. monocytogenes, then the only probable source of L. monocytogenes would be from exposure of the product during peeling and repackaging. However, the establishment's sanitation program may keep the numbers to a very low level, and 3 % sodium lactate included in the formulation would inhibit the growth of L. monocytogenes during the product's refrigerated shelf life. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels.

This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study combinations of antimicrobials were used, and in combination with hot water treatment. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80° C for 60 s. Storage at 4° C shows:

TREATMENT	LEVELS (%)	L. MONOCYTOGENES GROWTH INHIBITION
Sodium lactate	1.8	35-50 days no growth
Sodium lactate + sodium acetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Sodium diacetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Glucuno-delta-lactone	1.8 0.25	120 days no growth, 35-50 days growth reduction
Hot water treatment (80° C, 60 s) + Sodium lactate	1.8	Inoc. population reduced by 0.4-0.9 log CFU/cm^2, and 50-70 days growth reduction by 1.1-1.4 CFU/ cm^2
Hot water treatment (80° C, 60 s)		Increase in growth to about 6-8 logs in 50 days
Control, no treatment		Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days

*3 % of a 60 % (wt/wt) commercial solution.

Glass et. al., (2002) evaluated sodium lactate and sodium diacetate on wieners and cooked bratwurst containing both beef and pork supplied by a commercial manufacturer. Antimicrobial solutions used were sodium lactate and sodium diacetate singly or in combination at varying concentration. Wieners were repackaged in gas-impermeable pouches, then surface-inoculated with L. monocytogenes mixture on multiple areas of the surface of each link. Packages were vacuum-sealed and stored at 4.5° C for up to 60 days. Two types of cooked bratwurst from a commercial manufacturer were evaluated: bratwurst that was cured and naturally smoked and bratwurst that was uncured and unsmoked. Bratwurst was stored at 3 or 7° C for up to 84 days.

The surface treatment consisting of dipping wieners into solutions containing up to 6 % lactate and up to 3 % diacetate for 5 s did not delay pathogen growth, indicating that dipping wieners in the lactate/diacetate solutions is not an efficient way to apply the antimicrobials . However, the inclusion of lactates and diacetates in the formulation was found effective in inhibiting growth of L. monocytogenes. Results are as follows:

PRODUCT	Sodium Lactate (%)	Sodium diacetate (%)	L. monocytogenes levels (CFU/pkg)
Bratwurst uncured, unsmoked	3.4	0.1	Growth delayed for 4-12 weeks at 7 and 3° C storage, respectively.
	2.0	0.0	Growth delayed for 1-2 weeks at 7 and 3° C storage, respectively.
Bratwurst cured, smoked	3.4	0.1	Growth inhibited for 12 weeks at 7 and 3° C storage.
	0.0	0.0	Growth up to 1 log after 4 weeks at 7 and 3° C
Wieners	3.0	0.0	Growth inhibited for 60 days at 4.5° C
	1.0	0.1	Growth inhibited for 60 days at 4.5° C

Study by (Porto et al., 2002) used freshly processed peeled frankfurters in vacuum sealed packages obtained from a commercial manufacturer. Two formulations of links were used in the study: one with added 2 or 3 % potassium lactate and the other without added potassium lactate. Frankfurters were aseptically removed from their original package, repackaged, and inoculated with a mixture of L. monocytogenes. The packages were vacuum-sealed to 95 kPa and incubated at 4 and 10° C.

Results show that addition of 2 % or 3 % potassium lactate in frankfurters can appreciably enhance safety by inhibiting or delaying the growth of L. monocytogenes during storage at refrigeration or abused temperatures. The viability of the pathogen was influenced by pH, and the levels of lactate added, but not by the presence of indigenous lactic acid bacteria.

Potassium lactate (%)	Inoculum CFU/pkg	Storage temp °C)	Days Storage	L. monocytogenes levels (CFU/package)
2.0	20	4	90	Remained at about 1.6 log
3.0	20	4	90	Remained at about 1.4 log
3.0	500	4	90	Remained at about 2.4 log
0.0	20	4	90	Increased to about 4.6 log
0.0	500	4	90	Increased to about 5.0 log
2.0	20	10	60	Remained at about 1.4 log
3.0	20	10	60	Remained at about 1.1 log
0.0	20	10	60	Increased to about 6.5 after 28 days, declined to about 5.0 after 60 days
3.0	500	10	60	Remained at about 2.4
0.0	500	20	60	Increased to about 6.6 log after 40 days and declined to about 5.5 log after 60 days

II. Growth Inhibitor Packaging

Growth inhibitor packaging is an intervention, which delivers an active antibacterial agent to the surface of an encased sausage product. By incorporating this special coating onto the internal surface of cellulose casings, the antilisterial treatment is transferred to the surface of the processed meat/sausage during thermal processing. Upon removal of the casing, the treatment remains active on the meat surface, providing effective protection against inadvertent Listeria contamination during subsequent peeling, collating, and packaging processes. Growth inhibitor packaging used in conjunction with functional HACCP and Good Manufacturing Practices provides the industry with one more tool in their intervention strategy to control the risk of pathogen contamination in ready-to-eat meat and poultry products.

Studies on meat formulations for hot dogs using NOJAX® AL™ (Viskase) showed that use of the casings provide a lethality hurdle to the growth of Listeria monocytogenes, not just an inhibitory effect. The lethality impact is delivered within the first hours/days of the sausage/hot dog package life. This impact is dependent on many variables but is generally in the range of 1 – 2 log kill of L. monocytogenes at high levels of inoculation. This performance has been observed in challenge studies conducted on hot dogs drawn from commercial full-scale trials at a number of commercial processing plants. In high inoculation trials, NOJAX AL has been combined with conventional growth inhibiting additives, and as expected, the lethality impact is obtained and then maintained throughout the product life cycle. In these same trials, without growth inhibiting additives, this casing produces lethality but in several weeks the remaining L. monocytogenes begin to grow.

NOJAX AL is available in the U.S. having approval by both FDA and USDA for its key component, nisin. This GRAS component must be included in the ingredient statement via a label change request to the FSIS Labeling and Consumer Protection Staff. Because this is a naturally derived polypeptide, there are storage and use-by criteria that will have to be adhered to by the user for maximum benefit. Casing shelf-life is about 60-90days with a not to exceed 85° F.

This technology can be applied to most hot dogs and sausages that are encased in cellulosic casing. This casing intervention can be used in any instance were casing is used as a mold for processed meat and poultry during thermal processing. This would include cellulose, plastic, and possibly natural casing. As part of a manufacturer's decision to use this technology, benefits are: 1) no capital costs or new equipment; 2) no change in processing steps, plant reconfigurations or introduction of process bottlenecks—essentially processor transparent in all aspects of use except casing storage requirements; 3) no impact on flavor, texture, or package appearance, and 4) minor labeling change to ingredient statement.

Since this is a surface treatment, cost will be proportional to the surface to volume ratio of the product: the larger the sausage diameter, the lower the cost per pound. In general, economic analyses put the cost of this lethality intervention at about 2-3 cents per pound of finished product, with a mid-range target price of 2.5 cents per pound for a traditional 10-to-the-pound retail pack of hot dogs.

Janes et al., (2002) investigated the effect of nisin added to zein film coatings (Z) coated onto cooked ready-to-eat chicken against L. monocytogenes. Cooked chicken samples inoculated with L. monocytogenes were dipped into Z dissolved in propylene glycol or ethanol, with or without added nisin (1,000 IU/g) and/or 1 % calcium propionate and stored at 4 C or 8 C for 24 days. After 16 d at 4 C, L. monocytogenes was suppressed by 4.5 to 5 log CFU/g with zein film coatings with nisin. The most effective treatment in the study for controlling L. monocytogenes on the surface of ready-to-eat chicken was using edible zein film coatings containing nisin at a storage temperature of 4°C.

The use of film coatings in a processing plant would be to fully process the meat products then coat them with the films. Coating can be done by spraying or dipping the processed meat products and then allowing them to dry. Zein coatings on the meat products can be dried by circulating air around the meat product using a fan. Finally, the dried coated meat products can be packaged with the usual plastic film material and refrigerated. Nisin is presently not approved in the USA for use on ready-to-eat meat and poultry products, and this study has not been tested in commercial poultry processing conditions.

Some general observations from the published studies on antimicrobials:

- Lactates, acetates and diacetates were found more effective in inhibiting growth of L. monocytogenes when used in combination than when used singly.

- These antimicrobials were found more effective when used to the maximum allowable concentration. However, higher concentrations of antimicrobials used in the formulation may affect the sensory qualities of the product, such as flavor and texture, which would necessitate sensory evaluation of treated products.

- When used in combination, the amount needed to inhibit growth may be reduced.

- These antimicrobials were found to have listeriostatic activity more than listericidal activity, i.e. they prevent growth of the pathogen more than reduce the number of cells of the pathogen, and therefore may not be effective against gross contamination of a product. The establishment's sanitation program should control gross contamination of the processing environment and equipment. Addition of antimicrobials would be effective only as part of the overall HACCP strategy.

- Including these antimicrobials in the formulation was found to be more effective in inhibiting listerial growth than dipping products in solutions of antimicrobials.

- The antimicrobial activity of lactates and acetates when used singly or in combination is affected by the level of contamination of the meat product surface, and processing factors such as pH, moisture, water activity, fat, nitrite, salt content, time and temperature of storage, and packaging atmosphere.

- Application of the treatments used in these studies is limited to the formulations, products and treatments used in the studies. Applying these studies to other products and formulations may result in different rates of growth inhibition. Therefore the effectiveness of the antimicrobials used in these studies must be verified by the establishment for other processed meat products and other storage temperatures.

- Antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product. Currently the targeted commercial shelf life of refrigerated cooked meat products in the U.S.A. is 75 to 90 days.

- Using post-packaging thermal treatments in addition to antimicrobials was found to increase the total antilisterial effects of the antimicrobials.

- These antimicrobials were found to be more effective in smoked products formulated with sodium nitrite, or in products stored at strict refrigeration temperatures.

- Use of these antimicrobials may be a cost effective antilisterial method that very small establishments can use.

D. Sanitation Guidelines for Listeria monocytogenes

Control of L. monocytogenes is a challenge to a processing plant's sanitation program. The pathogen can grow in a damp environment, attach to surfaces that come into contact with raw or finished product, establish a niche and form biofilms. The sanitation program should include cleaning and sanitizing procedures that have been proven effective for the particular operation, separation of raw and RTE processing areas, traffic control, employee hygiene, and equipment flow and design among others.

Proper and effective sanitation involves both cleaning and verifying that the cleaning and sanitizing was effective. This involves developing and implementing written sanitation standard operating procedures (Sanitation SOP's). Sanitation SOP's could be viewed as the first step to designing a total system, including the HACCP plan, that will prevent, eliminate, or reduce the likelihood of pathogenic bacteria from entering and harboring in the plant environment. The Sanitation SOP's as described in 9 CFR 416.12 through 416.16, give detailed mandatory requirements for developing and implementing the sanitation program, while 416.17 describes how FSIS will verify that each establishment is meeting the Sanitation SOP regulations. In brief, the regulations require the following:

- **Development of Sanitation SOP's (416.12)** – Each establishment shall develop a written Sanitation SOP that describes all sanitation procedures to be performed each day, before and during operations with specific frequencies of each procedure and the responsible person for each task. It must also describe the cleaning process for all food contact surfaces, utensils, and equipment used to process your product(s). This document must be signed and dated by either the person responsible for the overall sanitation operations or a higher level employee in the establishment once it is implemented, and when any changes are made to the Sanitation SOP's.

- **Implementation of SOP's (416.13)** – All preoperational procedures identified in the Sanitation SOP shall be done daily, before processing operations start. Each procedure must be performed at the specified frequency and they must be monitored daily.

- **Maintenance of Sanitation SOP's (416.14)** – Each establishment shall routinely determine if the written Sanitation SOP is still effective in preventing direct product contamination and adulteration. If the Sanitation SOP is determined not to be effective because of changes in equipment, utensils, facility, operations, or personnel, changes in the procedures must be made to reflect changes.

- **Corrective Action (416.15)** – The appropriate corrective action(s) shall be taken when it has been determined by FSIS or by an establishment employee that the written Sanitation SOP has failed to prevent direct product contamination or adulteration of your product(s).

- **Recordkeeping Requirements (416.16)** – Daily records shall be maintained that describe how the sanitation activities were implemented and monitored, and all corrective actions; these records must be initialed and dated. Both computer records and paper records are appropriate however; additional controls may be needed to ensure the integrity of the electronic data.

- **Agency Verification (416.17)** – FSIS will verify the effectiveness and adequacy of the written Sanitation SOP's to ensure that they meet all of the regulatory requirements. This will be done by reviewing all records, direct observations, and microbial testing as deemed necessary.

I. General Procedures

An example of equipment and processing room cleaning using eight steps is outlined below. Cleaning should be increased and intensified during periods of construction.

1. Remove waste material. Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other solid debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly.

Equipment may need to be cleaned and sanitized again after re-assembly.

2. Wash and rinse floor.

3. Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or "set soils").

4. Clean and scrub equipment. Always at least use the minimum contact time for the detergent/foam. Written instructions should be provided on the location of possible niches and the cleaning method to use. CAUTION: Live steam for cleaning is not acceptable.

5. Rinse equipment (rinse in same direction as product flow).

6. Visually inspect equipment (repeat steps 3 and 4 if not clean visually or by testing such as ATP bioluminescence).

7. Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., chlorine, quaternary ammonia, etc.) may be more effective than steam for L. monocytogenes control. If steam heating equipment in an oven or tarp, the target internal temperature is 160° F and hold for 20-30 min. Portable high-pressure, low volume cleaning equipment (131°F (55°C) with 20-85 kg/cm^2 pressure and 6-16 liters/minute) can be used.

8. Remove excess moisture. This can be done most safely and efficiently by drying. Reduced relative humidity can speed the process. Avoid any possible cross-contamination from aerosol or splash if a method other than air drying is used. If cross-contamination is suspected, repeat steps 4 – 7.

II. Determining the Effectiveness of Sanitation Standard Operating Procedures (Sanitation SOPs)

The establishment should determine if the cleaning and sanitizing procedures used was effective by visual examination or testing or both.

1) Visual inspection of the equipment and environment. Visual inspection is the minimum means of determining the effectiveness of the sanitation standard operating procedures (SOPs). It can only detect observable contamination.

a. Visually verify that no meat or product residue is on the equipment, especially those product contact surfaces and areas that may serve as niches for bacteria,

before the start of operation.

b. Record the results of the visual inspection.

c. If any residue is noted, corrective action should be taken and recorded.

d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).

e. Visually verify that no meat or product residue is on the equipment, especially those product contact surfaces and areas that may serve as niches for bacteria, after post-processing cleanup.

2) Visual inspection and use of ATP bioluminescence testing. Visual verification combined with ATP testing can determine both observable contamination and contamination from bacteria and meat/poultry residues that may not be visually detectable. The combined methods are more effective in determining the effectiveness of the sanitation SOP.

a. The ATP test indicates the presence of both bacteria and meat or poultry residues and can be used to verify that no meat or poultry residue is on the equipment, esp. those product contact surfaces and areas that may serve as niches for bacteria, before the start of operation.

b. Record the results of the ATP test and visual inspection.

c. If any residue is noted or observed visually or the ATP test indicates an insanitary condition, corrective action should be taken and recorded.

d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).

e. By ATP testing and visual examination, verify that no meat or product residue is on the equipment, esp. those product contact surfaces and areas that may serve as niches for bacteria, at the end of the shift.

3) Visual inspection and total plate counts (TPC). Visual verification combined with TPC can determine both observable contamination and the level of bacterial contamination. Since TPC results cannot be obtained at the time of inspection, its value is the measurement of the level of contamination. The level of contamination may assist the

establishment in determining the source of contamination and the effectiveness of the sanitation SOP.

a. Visually verify that no meat or product residue is on the equipment, esp. those product contact surfaces and areas that may serve as niches for bacteria, before the start of operation.

b. Use swabs or RODAC plates for sampling food contact surfaces, non-food contact surfaces, and the processing environment.

c. Record the results of the visual inspection.

d. If any residue is noted, corrective action should be taken and recorded.

e. Record the TPC when analysis complete.

f. The monitoring record should be designed to show any trends of insanitary conditions as determined by visual inspection or TPC. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).

g. Visually verify that no meat or product residue is on the equipment, especially those product contact surfaces and areas that may serve as niches for bacteria, again after post-processing cleanup.

III. Traffic Control

Controlling the movement of personnel and raw and finished products will help prevent cross-contamination of finished products by raw materials and personnel. The following are steps that should be taken for traffic control:

1. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets and refuse containers between raw and finished product areas.

2. Control traffic into and within the RTE areas

   a. If possible, use air locks between raw and RTE areas.

   b. Clean dry floors are preferable to foot baths.

   c. If foot baths are used:

      i) Wear rubber or other non-porous boots.

ii) Maintain them properly.

iii) Solutions should contain stronger concentrations of sanitizer than normally used on equipment.

(1) For example, 200 ppm iodophor, 400-800 ppm quaternary ammonia compound).

(2) CAUTION: Chlorine is not recommended as it is too quickly inactivated esp. if cleated boots are used. Monitor and maintain its strength if used.

iv) Use a minimum depth of 2 inches.

d. Foam disinfectant spray on floor as people or rolling stock enter the room.

3. Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.

a. Use different color smocks or helmets for raw and RTE areas so the workers and garments in the raw and RTE areas are readily distinguishable.

b. Remove outer garments (e.g., smocks) when leaving RTE areas.

4. Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. If not possible, there should be a time separation when utensils for raw processing/handling are cleaned after RTE. The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment.

5. Do not permit maintenance employees in RTE areas during operations if possible. If not possible:

a. Consider the need to cease operations until a full cleaning and sanitizing is done, or,

b. Maintenance personnel must change outer clothing and any other soiled clothing, use separate tools for raw and RTE areas (or wash and sanitize tools and hands prior to entering RTE areas) and wear only freshly cleaned/sanitized footwear in such areas.

6. Use separate equipment, maintenance tools and utensils for the RTE and raw areas. If not possible, there should be a time separation between raw processing/handling and RTE processing.

7. Pallets can serve as a source of cross-contamination – pallets for raw materials should not be used in RTE areas or used for finished product.

8. Drains from the "dirty" or "raw" side should not be connected to those on the "clean" or "cooked" side.

IV. Employee Hygiene

Employee hygiene is the responsibility of both the individual and management. The employee is responsible for preventing contamination of food products and the management is responsible for ensuring the employee is properly trained and maintains good practices.

Employee responsibilities and actions should include:

1. Use a 20 second hand wash after using restroom facilities.

2. Wash hands before entering the work area, when leaving work area, and before handling product.

3. If gloves are worn:

    a. Gloves that handle RTE product must be disposable.

    b. Dispose immediately and replace if anything other than product and food contact surface is touched.

    c. Dispose of gloves when leaving the processing line.

4. Remove outer clothing when leaving RTE areas.

5. Do not wear RTE clothing inside bathrooms or cafeterias.

6. Do not store soiled garments in lockers.

7. Do not eat in the locker room or store food in lockers.

8. Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times.

Management responsibilities should include:

1. Providing hand washing facilities at proper locations.

2. Ensuring the employee receives proper hygiene instruction before starting – use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway

sanitizing systems.

3. Developing a system for monitoring employee hygiene practices.

4. Developing a system for tracking the training, tests taken, and certification.

5. Retraining employees before placing back into production.

V. Sanitizers

Cleaning and sanitizing are vital to any effective sanitation program. Through cleaning should be followed by sanitizing. Generally, the cleaning step is to remove all waste materials and soils, and the sanitizing step is to destroy all microorganisms. Careful consideration should be given to selecting both, cleaning and sanitizing solutions. It is important to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastics, and solutions that are effective in destroying the type of bacteria commonly associated with the type of products you produce. Acidic quaternary ammonia, chlorine dioxide, and peracetic acid compounds were found to be the most effective in destroying attached organisms (Krysinski, L.J., et al;1992).

To aid the cleaning and sanitizing employee in properly selecting and applying the product for its intended application, products that are specifically designed to clean soils in meat and poultry establishments and that are color coded for each application should be selected. An example of this kind of product is Quorum (Ecolab, Inc., St. Paul., MN). Another help for the cleaning employee is to select products with product label and instructions written in English and Spanish.

VI. Sources and Control of Listeria monocytogenes Contamination

Listeria monocytogenes is constantly introduced into the processing environment. It may be introduced in incoming raw product, processing environment or by employees. The following are steps that should be taken to prevent contamination of product with L. monocytogenes after cooking:

1. Verify that cooking or other control measures will eliminate L. monocytogenes. Most meat products implicated in human listeriosis are contaminated with L. monocytogenes after these measures are applied. Undercooked product may introduce L. monocytogenes to food contact surfaces or the environment after cooking and before packaging.

2. Prevent contamination of product contact surfaces and prevent the formation and growth of L. monocytogenes in a niche, especially in areas after the cooking step. A niche is a harborage site within the plant that provides an ideal place for L. monocytogenes to establish and multiply. Certain strains can become established in a processing environment for months or years. L. monocytogenes can be spread from

these sites and re-contaminate food or food contact surfaces between the cooking step and packaging.

Examples of reservoirs and harborages of L. m nocytogenes in RTE processing environment
Hollow rollers on conveyors
On-off valves and switches
Worn or cracked rubber seals around doors
Vacuum/air pressure pumps, lines, hoses
Cracked tubular rods on equipment
Air filters
Drains
Condensate from refrigeration unit
Floors
Standing water
Open or gulley drains
Ceilings and over head pipes
Overhead rails and trolleys
Chiller and passageway walls and doors
Chiller shelving
Roller guards
Door handles
Boots
Ice makers
Saturated Insulation
Trolley and forklifts
Compressed air in-line air filters
Trash cans
Cracked hoses
Wet rusting or hollow framework
Walls that are cracked, pitted, or covered with inadequately sealed surface panels
Maintenance and cleaning tools
Space between close fitting metal-to-plastic parts
Space between close fitting metal-to-metal parts

3. Examine routes taken by products from heat treatment, or other control to eliminate L. monocytogenes, to final packaging.

Typical sites of L. monocytogenes contamination
Filling or packaging equipment
Solutions used in chilling food
Peeler, slicer, shredders, blenders, brine chill, casing removal system, scales, or other equipment used after heating and before packaging
Spiral or blast freezers
Conveyors
Bins, tubs, or other containers used to hold food for further processing

4. Frequently clean sites known to support L. monocytogenes using effective cleaning procedures. The following is a recommended frequency for cleaning and sanitizing processing equipment and the plant environment:

    a. Daily

        i. All processing equipment

        ii. Floors and drains

        iii. Waste containers

        iv. Storage areas

    b. Weekly

        i. Walls

    c. Weekly/monthly

        i. Condensate drip

        ii. Coolers

    d. Semiannually

        i. Freezers

5. Maintain equipment and repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.

6. Implement a microbial sampling program to monitor and detect sources of L. monocytogenes in the environment. Environmental testing is more effective then product testing alone to monitor and detect Listeria in the environment.

7. Design a sampling scheme to locate a niche before L. monocytogenes becomes established.

    a. Use a statistically designed sampling plans based on probability, or

    b. Use prior experience and familiarity with processing conditions to determine the most likely source of contamination. All processing equipment would sampled but with a bias toward those areas identified as possibly problematic.

    c. Review at least the last month of results to determine trends or to revise sampling scheme.

    d. When a problem area is detected, take corrective action on the affected processing line as opposed to adjacent lines in the area. Target the area corresponding to the line associated with the findings for cleaning. Contamination is usually line specific.

8. Take follow up tests to monitor the area and verify the cleaning results.

Equipment Design

Selecting the appropriate equipment enhances cleaning operations and help control L. monocytogenes in the plant environment. The following are steps to take when selecting equipment:

1. If possible, develop a team (persons from Quality Assurance, Sanitation, Maintenance, and Production) to evaluate equipment before it is purchased or set specific requirements for plant equipment.

2. Have the equipment reviewed by a third-party expert if possible.

3. Select equipment designed to minimize sites on the exterior or interior where L. monocytogenes can grow.

4. Select equipment designed to enhance cleaning.

    a. All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled.

        i. Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible.

        ii. Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk.

b. Equipment should be self-draining or self-emptying.

5. Select food contact surfaces that are inert, smooth and non-porous.

6. Maintain equipment and machinery by adopting regular maintenance schedules.

    a. Damaged, pitted, corroded, and cracked equipment should be repaired or replaced.

        i. Repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.

        ii. Use separate tools for RTE equipment only. Sanitize them before and after each use.

    b. If compressed air is used, maintain and replace in-line filters regularly.

    c. Use lubricants that contain listericidal additives such as sodium benzoate. L. monocytogenes can grow in lubricants that are contaminated with food particles.

    d. Use the appropriate cleaners and sanitizers on surfaces or equipment.

Thoroughly clean and sanitize equipment prior to using in production. Pathogens can live on surfaces that appear visually clean.

VII. Determining the Effectiveness of Sanitation Procedures (Testing for Listeria monocytogenes, Listeria spp. or Listeria-like organisms)

Establishments can verify the effectiveness of their sanitation program by testing food contact surfaces (FCS) and other relevant environmental surfaces. This section includes recommended testing of food contact surfaces for each alternative, a guide to testing for Listeria spp or Listeria-like organisms, and an example of a hold and test scenario.

A. Food Contact Surface and Environmental Testing

The sampling frequencies for FCS testing suggested below should be increased if there is construction, change in the HACCP plan, roof leaks, or other event that could change or increase the probability of product contamination. Samples should be taken at least 3 hours after the start of operation. Up to 5 samples may be composited. However, it is recommended that like surfaces be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The sample locations for the composite sample should be noted to assist in determining the site of contamination. Environmental samples other than food contact surface samples should be taken by the establishment. This will also assist the establishment in locating potential sources of contamination.

1. Alternative 1 – Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of L. monocytogenes.

   i) Conduct tests of food contact surfaces for L. monocytogenes, Listeria spp., or Listeria-like organisms at least twice a year.

   ii) Sample at least 1 square foot area for each surface, if possible.

   iii) Record the test results.

   iv) If test results are positive for L. monocytogenes or Listeria-like or organisms:

      (1) Take corrective action which should include an intensified cleaning and sanitizing.

      (2) Record the corrective actions taken.

      (3) Retest the food contact surface.

      (4) Repeat corrective action and testing until samples are negative for L. monocytogenes or Listeria-like organisms.

      (5) More than 3 consecutive positives should initiate intensified testing.

2. Alternative 2 - Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of L. monocytogenes.

   i) If a post-lethality treatment is used, conduct tests of food contact surfaces for L. monocytogenes, Listeria spp., or Listeria-like organisms at least quarterly.

      (1) Sample at least 1 square foot area for each surface, if possible.

      (2) Record the test results.

      (3) If test results are positive for L. monocytogenes or Listeria-like organisms:

         (a) Take corrective action which should include an intensified cleaning and sanitizing.

         (b) Record the corrective actions taken.

         (c) Retest the food contact surface.

(d) Repeat corrective action and testing until samples are negative for L. monocytogenes or Listeria spp., or Listeria-like organisms.

ii) If an antimicrobial agent is used, conduct tests of food contact surfaces for L. monocytogenes, at least quarterly.

(1) Sample at least 1 square foot area for each surface, if possible.

(2) Record the test results.

(3) If 3 consecutive tests of food contact surfaces are positive for Listeria spp., or Listeria-like organisms:

(a) Take corrective action which should include an intensified cleaning and sanitizing.

(b) Record the corrective actions taken.

(c) Hold the product.

(d) Test product for L. monocytogenes.

(e) Retest the food contact surface.

(f) Repeat corrective action and testing until food contact surface test results are negative for L. monocytogenes, Listeria spp., or Listeria-like organisms.

(g) If the test results for the product are positive for L. monocytogenes,

(i) Recall the product, if necessary, and

(ii) Destroy the product, or

(iii)Re-work the product with a process with a process that is destructive of L. monocytogenes.

3. Alternative 3 – Use of sanitation control measures only to prevent contamination of product with L. monocytogenes.

i) Conduct tests for L. monocytogenes, Listeria spp., or Listeria-like organisms at least four times per month per line for large establishments, two times per month per line for small establishments, and once per month per line for very small establishments. (A large establishment is one that employs more than 500 employees, a small establishment is one that employs from 10 to 499

employees, and a very small establishment is one that employs less than 10 employees and one grossing less than $ 2.5 million in sales.)
FSIS regards production volume as a more important risk factor than establishment size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break-off between high volume and low volume to be approximately 1.3 million pounds yearly, derived from the RTE survey.

ii) Sample at least 1 square foot area for each surface, if possible.

iii) Record the test results.

iv) If the first test result of a food contact surface is positive for Listeria spp., Listeria-like organisms, record the corrective actions taken.

v) For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for Listeria spp., Listeria-like organisms:

(1) Take corrective action which should include an intensified cleaning and sanitizing.

(2) Record the corrective actions taken.

(3) Hold the product or recall the product (see hold and test scenario below).

(4) Test for L. monocytogenes at a rate that provides a level of statistical confidence that the product is not adulterated.

(5) Retest the food contact surface each day until the test result is negative for Listeria spp., Listeria-like organisms.

(6) Continue to hold each day's production lot until the test results for the food contact surfaces are negative.

(7) If the test results for the product are positive for L. monocytogenes,

(a) Recall the product, if necessary, and

(b) Destroy the product, or

(c) Re-work the product with a process with a process that is destructive of L. monocytogenes.

vi) For establishments producing products other than hotdogs or deli meats, if 3 consecutive tests of food contact surfaces are positive Listeria spp., or Listeria-like organism:

(a) Take corrective action, which should include an intensified cleaning and sanitizing.

(b) Record the corrective actions taken.

(c) Hold the product.

(d) Test product for L. monocytogenes.

(e) Retest the food contact surface.

(f) Repeat corrective action and testing until food contact surface test results are negative for L. monocytogenes, Listeria spp., or Listeria-like organisms.

(g) If the test results for the product are positive for L. monocytogenes,

(i) Recall the product, if necessary, and

(ii) Destroy the product, or

(iii)Re-work the product with a process with a process that is destructive of L. monocytogenes.

FSIS realizes that some establishments' sanitation and testing program may be exceeding the guidance provided above. In this case, FSIS may put the establishment's product into a lower expected frequency for verification testing within the appropriate sampling frame under the following conditions:

a) The establishment addresses major construction within its control program such that the intensity of sanitation and the verification testing procedures are increased during the time of the disruption and for a period of time following the disruption until the data demonstrate that there is no harborage of L. monocytogenes or its indicator organisms.

b) The establishment has a good history of proper maintenance of the control program, particularly in regards to such things as the sanitation program, reacting to conditions that might indicate that harborage of L. monocytogenes or its indicator organisms is occurring, and appropriately reacting to positive test results for L. monocytogenes or indicator organisms.

B. Guidelines for Listeria spp. and Listeria-like testing for food contact surfaces and other environmental testing

Listeria spp. or Listeria-like organisms are the indicator organisms to be used for L. monocytogenes because their presence indicates the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that L. monocytogenes is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator tests for L. monocytogenes. Results from these tests do not indicate the presence or absence of the pathogen. However, testing for these organisms can be done in addition to the testing for L. monocytogenes or its indicators to monitor the effectiveness of the cleaning procedures and level of contamination during processing. FSIS microbiology laboratory methods are available and can be downloaded at http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm

1. Listeria spp. testing

   i) The methodology must employ enrichment prior to Listeria spp. screening.

   ii) Listeria spp. screening is conducted from the enrichment using an immunoassay, nucleic acid assay, or equivalent Listeria spp.-specific technology.

   iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of Listeria spp. and/or L. monocytogenes. Specific validation for environmental sampling is encouraged but not a requirement at this time.

2. Listeria-like indicator testing

   i) The methodology must employ enrichment prior to Listeria-like indicator screening.

   ii) The Listeria-like indicator positive screening result may be indicated by the presence of suspect Listeria spp. colonies after selective plating, or may be indicated by biochemical changes to screening broths (*e.g.*, Fraser Broth) that are consistent with the potential presence of Listeria spp.

   iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of Listeria spp. and/or L. monocytogenes. Specific validation for environmental sampling is encouraged but not a requirement at this time.

   iv) Aerobic plate counts, ATP assays and other indicator organism tests that do not specifically meet the above requirements may be employed by the

establishment for supplemental sanitation testing. However, these tests do not meet the FSIS expectations for Listeria spp. or Listeria-like indicator food contact and other environmental surface testing programs that may be conducted by the establishment.

C. Hold and Test Scenario

Assuming it takes to 3 days to obtain a test result for Listeria spp., or Listeria-like organisms:

Day 1 – Take food contact surface (FCS) samples

Day 4 – FCS sample positive (from Day 1) for Listeria spp., or Listeria-like organisms.

- ✓ Take Corrective Action
- ✓ Intensified cleaning and sanitizing
- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Continue production.

Day 7 – Second FCS sample (from Day 4) positive for Listeria spp., or Listeria-like organisms.

- ✓ Take Corrective Action
- ✓ Intensive cleaning and sanitizing
- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Hold and test product (for L. monocytogenes) for lot implicated in the positive FCS testing.
- ✓ Continue production, hold product from the day's production

Day 8 –

- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 9 –

- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 10 –

If FCS sample (day 7 sample) is negative for Listeria spp., or Listeria-like organisms.

- ✓ Continue production and release product from days 7, 8 and 9 production

- ✓ Resume FCS testing according to frequency stated in sanitation program

If FCS sample (day 7 sample) is positive for Listeria spp., or Listeria-like organisms:

- ✓ Hold product from day 10 production.
- ✓ Test product from days 7, 8, 9, and 10 for L. monocytogenes
- ✓ Take corrective action
- ✓ Intensive cleaning and sanitizing
- ✓ Take FCS sample-- target most likely source of contamination, and additional tests in surrounding FCS area

Day 14 – If product is positive for L. monocytogenes, do not release product to commerce and destroy product, or rework product with a process that is destructive of L. monocytogenes.

Every time there is a second or more (consecutive) FCS positive, product is held and tested for L. monocytogenes. Only product lots implicated with a second or more consecutive FCS positive are held and tested. Every time there is a product positive for L. monocytogenes, product is recalled, if not held, and destroyed or reworked with a listericidal process. Once the FCS testing is negative, implying that the corrective action is working, production is continued.

Repeated FCS positives would imply a critical sanitation problem and the establishment need to conduct intensive testing and intensive cleaning and sanitizing. The establishment should have provisions in their FCS testing program for these kinds of situations.

D. Sentinel Site Program Example

Some establishments have adopted a sentinel site program for the control of L. monocytogenes in RTE meat and poultry products. A sentinel site program is similar to traditional Listeria control programs – separate testing programs for the environment and food contact surfaces and increasingly aggressive corrective actions to eliminate Listeria when it is detected. The distinctive characteristic of this control program is that in the case of a positive Listeria test result for a food contact surface area, the sanitation of that particular area will be included in the HACCP plan as a CCP. The CCP is removed when the establishment determines that the food safety hazard has been eliminated and is not reasonably likely to occur.

The CCP is the sanitation program for the particular site and food contact surface sampling as verification of the CCP. If a food contact surface or non-food contact surface tests positive for Listeria spp. or Listeria-like organisms, testing is intensified in the area of the positive.

If a non-food contact surface sampling site is found to be positive for Listeria spp. or Listeria-like organisms during routine monitoring, intensified sampling is initiated as

soon as possible. Under intensified sampling, three samples per day (one each at pre-op, 1st shift, 2nd shift) are analyzed until a total of nine consecutive samples have been taken and are negative for Listeria spp. or Listeria-like organisms at that particular site. Swabs are analyzed for each day of production. If a sample finding is positive, testing of that site continues until nine consecutive samples are negative for Listeria spp. or Listeria-like organisms. Once nine consecutive samples are found negative, that site will returned to routine sampling.

Similarly, the food contact surface site that initially tests positive for Listeria spp. or Listeria-like organisms will be placed under intensified testing. If nine consecutive samples under the intensified testing are negative for Listeria, that site is returned to routine monitoring. However, if the food contact surface tests positive under the initial intensified sampling, sanitation for that area is designated as a CCP since Listeria cannot be considered a hazard not reasonably likely to occur. The site testing positive for Listeria would be considered a suspect harborage for L. monocytogenes and corrective actions taken. Testing becomes the verification step.

Intensified sampling under the CCP requires that 3 samples per day (one each at pre-op, 1st shift, 2nd shift) be taken until nine consecutive samples are negative for **both** Listeria spp. and L. monocytogenes. If a sample is positive for *Listeria* spp. but negative for L. monocytogenes, additional sampling days are added (3 samples per day) until nine consecutive samples are negative for both Listeria spp. and L. monocytogenes. All product that has contact with that particular site must be placed on hold pending testing results.

If nine consecutive samples are negative for Listeria spp. and L. monocytogenes, the site can be returned to routine sampling. Product can be released when the line and production date receive negative test results for L. monocytogenes. Any sites testing positive for L. monocytogenes would require testing of the product.

Sentinel Site Program
Example Flowchart

1. Routine Environmental Sampling
    a. 5 samples/line/week
        i. 3 – food contact surface samples
        ii. 2 – non-food contact surface samples
        iii. Listeria spp.
2. Non-food Contact Surface Testing
    a. If negative for Listeria spp., continue Routine Environmental Testing
    b. If positive for Listeria spp., intensify sampling
        i. Collect 3 samples/site/day for 3 consecutive days for Listeria spp. (9 consecutive samples)
        ii. If 9 consecutive samples are negative for Listeria spp., return to Routine Environmental Sampling
        iii. If any sample is positive, continue sampling 3 samples/site/day until 9 consecutive samples are negative
3. Food Contact Surface (FCS) Testing
    a. If negative for Listeria spp., continue Routine Environmental Testing.
    b. If positive for Listeria spp., intensify sampling.
        i. Collect 3 samples/site/day for 3 consecutive days for Listeria spp. (9 consecutive samples).
        ii. If 9 consecutive samples are negative for Listeria spp., return to Routine Environmental Sampling.
        iii. If any sample is positive, make sanitation for that site a CCP

4. CCP Testing

    a. Collect 3 samples samples/site/day for 3 consecutive days for Listeria spp. **and** L. monocytogenes (9 consecutive samples).

    b. If 9 consecutive samples are negative for Listeria spp. **and** L. monocytogenes, return to Routine Environmental Sampling and eliminate the CCP.

    c. If a sample is positive for Listeria spp. but negative for L. monocytogenes

        i. Place product on hold

        ii. Release product if site and production date have negative results for L. monocytogenes

        iii. Continue testing until 9 consecutive samples are negative for Listeria spp. **and** L. monocytogenes, then return to Routine Environmental Sampling and eliminate the CCP

    d. If any sample is positive for L. monocytogenes, test the product for L. monocytogenes

        i. Reprocess or destroy product testing positive for L. monocytogenes

E. References

A. Post-lethality Treatments and Antimicrobial Agents

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Foster Farms

PURCHASE ORDER
CHANGE

PO NO: C 252857
ISSU DTE: 04/29/97 PAGE: 1
CHNG DTE: 05/02/97 REV: 2

BILL TO:
FOSTER POULTRY FARMS
ACCOUNTS PAYABLE
P O BOX 457
LIVINGSTON, CA 95334

COMMUNICATIONS TO:
FOSTER POULTRY FARMS
PURCHASING DEPARTMENT
P O BOX 457
LIVINGSTON, CA 95334-0457

VENDOR: 167672
UNITHERM FOOD SYSTEMS INC
1188 WEST HARTFORD
PONCA CITY OK 74601

BUYER: JOHN P. JETTON
TEL: 209-394-6975

SHIP-TO:
FOSTER FARMS
FTP II PLANT
711 F STREET
TURLOCK, CA. 95380
ATTN: JIM THEIS

VENDOR TERMS:
NET 30 DAYS

TAX:
ALL ITEMS SUBJECT TO CALIFORNIA STATE SALES TAX.

SHIP-VIA: CC
FRT TRMS: PREPAY AND ALLOW
FOB: TURLOCK

CONFIRMING ORDER - DO NOT DUPLICATE

RECEIVING APPROVAL FOR THIS ORDER WILL BE AUTHORIZED BY THE REQUESTOR.

LINE	QUANTITY	UOM	ITEM ID	UNIT PRICE	EXT PRICE
1	1	LOT	SEE DESCRIPTION BELOW CAPITAL EQUIPMENT-PLANT	$288,288.88888	$288,288.00

UNITHERM RAPIDFLOW II RF-2 - 2 ZONE
WITH C.I.P.
PRICE INCLUDES:
1. INSTALLATION - 2 ENGINEERS, 2 DAYS
2. DELIVERY CHARGE
3. LIQUID SMOKE APPLICATION SYSTEM

SEE ATTACHMENTS "A", "B", "C", AND "D" FOR SPECIFICATIONS, TERMS AND CONDITIONS, OPTIONS AND RECOMMENDED SPARE PARTS LIST, RESPECTIVELY.

I ACKNOWLEDGE RECEIPT & ACCEPTANCE OF THIS ORDER

SIGNED _____ PRESIDENT 05-05-97

Recommended spare parts for 2-Zone RapidFlow will be supplied as consignment stock.

Delivery will be six to seven weeks from our receipt of your order and deposit.

THIS PURCHASE ORDER constitutes an offer by Foster Farms to purchase the above described goods or services, at the prices and upon the terms stated, and UPON THE TERMS AND CONDITIONS SET FORTH ON THE REVERSE SIDE HEREOF. READ THE REVERSE SIDE before accepting this order. ANY VARIATION OF SAID TERMS AND CONDITIONS will invalidate this Purchase Order, unless later agreed to by Foster Farms.

VENDOR

EXHIBIT 7A

U-03655

UNITHERM RAPIDFLOW II CONTINUOUS CONVECTION OVEN RF2
SPECIFICATIONS

Belt Height:	40"
Belt Width:	40"
Belt Type:	Flat flex wire belt
Overall Length:	20'
Cooking Length:	17'
Drive Motors:	1 off. SEW geared motor. IP 55 (1.3KW)
Belt Speed:	2 minute minimum; 4 hour maximum
Circulation Fans:	6 off, stainless steel impeller (6 x .075KW) Balanced by UNITHERM to provide even heat across entire belt.
Steam Injection System:	Into cooking chamber. Nominally 80 kgs per hour maximum at 2 bar dry saturated. (Indepedently Controllable)
Extraction Fan:	2 off. Bifurcated, 2000 cfm variable (0.75KW). Stainless steel construction.
Belt Washer (Continuous):	High pressure (25 bar) pump. Adjustable weir plate within washer to regulate water usage/ effluent discharge. Pump close-coupled to 15 KW drive motor.
Heating System:	Compromised of 48 x 2 kW finned incalloy elements per zone. Elements designed to maximized efficient heat t transfer (192 KW total heating load).
	Elements controlled via electronic thyristor drive to maximize energy efficiency. To maximize start-up time, full energy usage allows the oven to reach maximum temperature, (350°C) within 15 minutes from cold.
	PID temperature controllers within each zone allow accurate set point control of +/- 1°C.

ATTACHMENT "A"

A 2117

U-05656

Fire Protection Systems:	Operated by a solid-state, approved fire detector. Twin systems, steam at nominally 6 bar to flood the lower chamber and cooking area. Mains water into the oven top canopy. Pressure switched ensure pressure available to allow machine to operate.
General Construction:	All AISI 304 stainless steel. Main framework constructed from 40 x 40 RHS. Inner chamber allowed to "Free Float" for expansion purposes. Height adjustable, self-leveling feet fitted. Outer canopies hinged to allow cleaning. During hygiene, all belt support rods are easily removed and refitted. Fat collection tray in lower cooker chamber with 3" - diameter outfeed pipe to drain/collection fans are removable for hygiene. All pipework has demountable fittings to allow hygiene.
Control Panel:	Stainless steel IP 65, clear macrolon cover over door furniture and controllers. Visual display of temperature in each zone. Visual display of belt speed (frequency). General control gear telemecanique.
Electrical Components:	Where possible, electrical components will be Allen Bradley.

/A 2118

ATTACHMENT "A"

U-05657

TERMS AND CONDITIONS

1. 40" wide 2-Zone RapidFlow Continuous Convection Oven will produce:

   A. 4 pieces across the belt x 17 pieces along the belt
   = 68 pieces in the oven at any one time

   B. 68 pieces x 6 (10 minute dwell) = 408
   408 x 9 lbs. = 3,672 lbs. per hour

UNITHERM guarantees at a volume of 3,672 pounds per hour of nine (9) pound turkey breast product as tested at UNITHERM, to match this volume against the color definition agreed at UNITHERM.

   C. At a 3 minute dwell for the mailose product or carmel, the throughput will guaranteed at 10,000 lbs. per hour with the same color definition agreed to at UNITHERM with the 9 lb. Turkey Breast Product as tested.

   D. The guaranteed shrink will be 1 - 3.5 percent from the point of entering the oven to exit.

   E. Guarantee that the internal temperature of the product, which is 37° - 40° F going in to the oven, will not have risen above 40°F at time of exiting the oven.

   D. UNITHERM guarantees that Foster Farms will receive a full refund of the price of the oven upon request, on agreement of failure on the performance stated above.

2. UNITHERM warrants the fabricated metal for 20 years, specifically against corrosion and fatigue. In the event of a claim, a sliding depreciation scale would be applied. UNITHERM would elect to repair or replace a component. The warranty does not cover wear and tear from collision in the unit's environment.

3. Terms of payment should read 1/3 with the order, 1/3 prior to shipment on approval of process at Ponca City, and the remaining 1/3 within 15 days of delivery. In the event that the machine is not commissioned within 15 days as a result of UNITHERM progress, the payment may be retained until the unit is in production.

4. Foster Farms agrees to run 2,000 lbs. of product through the oven at Ponca City ensuring that the oven is ready to run upon arrival. Foster Farms will allow for 2 days of training for their maintenance staff at Ponca City.

ATTACHMENT "B"

A 2119

These options good for 12 months (1 year) from date of Purchase Order #C252057.

FUTURE OPTIONS

(Good for Two (2) Years from the date this purchase order (#C252057) is signed)

OPTION 1:
BAG STRIPPER
The product is conveyed through a washer and then onto the injection station where filtered, compressed air is injected to separate the casing from the product. The product is then conveyed through a slitter where the knives are depth-controlled to prevent scoring of the meat, and individually follow the contour of the product to provide uniform slitting of the casing. The product is then conveyed to a casing removal station where the separated and slit casing is manually removed.
Price: $23,000

OPTION 2:
IMPINGEMENT CHILLER
The chiller is 30 feet long with a 40" - wide belt, including a belt wash and drying system to prevent freezing after washing. (If this footprint is prohibitive, an alternative chiller can be designed and quoted.)
Price: $175,000.00

OPTION 3:
AUTO-LOADER
Price: $36,500.00

ATTACHMENT "C"

A 2120

RECOMMENDED SPARE PARTS LIST
UNITHERM TWO-ZONE RAPID FLOW

Part No.	Description	Qty. Used	Price $; Each/Per m
RA-10000A	Wire Belt 3/8" Pitch	45m	$259.20
RA-10010	29T Belt Sprocket	14	$ 70.56
	R635DT 90 L8-2	1	$3,768.00
	0.3/1.3 kW Motor		
RA-10030	80mm dia. 55 Roller	1	$216.00
RA-10040	50m dia. 55 Roller	1	$105.00
RA-8512	25 dia. DODGE Pillow Block	6	$163.20
	SNP 25 Coated Brg	4	$148.80
XS-8400	3/8" Duplex Sprocket	1.5m	$10.46
XS-8307	57T Duplex Sprocket	1	$76.80
XS-8302A	19T Duplex Sprocket	1	$37.30
U-2550/B/15	Idler Shaft	2	$720.00
U-2550/B/16	Drive Shaft	2	$720.00
RA-10045	55 Recirculation Axial Fan	9	$5,040.00
XE-8511LN	2kW Heating Element	144	$350.00
	Spray Heads 3/4" NPT1	12	$840.00
	Diaphragm Pump C.I.P.	3	$1,372.00
	Pump C.I.P.	3	$7,104.00
ED-24400	PT100 Probe	3	$235.00
ET-29319	Thyristor Unit	3	$7,152.00
	Thyristor Fuse	3	$158.40
ET-30125	Temperature Controller	3	$912.00
	Transformer 3KVA	1	$316.00
EC-21910	15 kW Contractor	1	$273.60
ER-27200	Pilz E/Stop Unit	1	$792.00

ATTACHMENT "D"

A 2122

U-05660

EC-21900	4 kW Contractor	13	$96.00
EE-247705	Cabinet Fan	4	$74.00
EE-24707	Fan Filter	4	$50.88
	600A Panel Isolator	1	$3,153.60
	600A Isolator Fuse	3	$369.60
ER-27060	On Delay Timer	1	$174.24
ES-28305	Safety Switch	27	$244.80
EI-25810	.075kW Inverter	3	$1,924.80
	1.5kW Inverter	1	$2,236.80
EC-22147	150A Contractor	3	$1,296.00
ED-24053	Fire Probe	6	$1,209.60
	50A Fuse	40	$4.61
EC23210	Hi Temp Cable	80	$16.32
EC-21002	Hi Temp Lugs	60	$0.86
ES-27891	Remote E/Stop	4	$108.72
PU-10000C	Belt Wash Pump	1	$12,960.00
XA-85521	Belt Wash Nozzle	50	$9.12
XW-8064	UHMWP Snap-on Strip	10	$2.40

A 2123

ATTACHMENT "D"

TOTAL P.18

U-05661

Fire Protection Systems:	Operated by a solid-state, approved fire detector. Twin systems, steam at nominally 6 bar to flood the lower chamber and cooking area. Mains water into the oven top canopy. Pressure switched ensure pressure available to allow machine to operate.
General Construction:	All AISI 304 stainless steel. Main framework constructed from 40 x 40 RHS. Inner chamber allowed to "Free Float" for expansion purposes. Height adjustable, self-leveling feet fitted. Outer canopies hinged to allow cleaning. During hygiene, all belt support rods are easily removed and refitted. Fat collection tray in lower cooker chamber with 3" - diameter outfeed pipe to drain/collection fans are removable for hygiene. All pipework has demountable fittings to allow hygiene.
Control Panel:	Stainless steel IP 65, clear macrolon cover over door furniture and controllers. Visual display of temperature in each zone. Visual display of belt speed (frequency). General control gear telemecanique.

ATTACHMENT "B"

A 2124

U-05662

Foster Farms

PURCHASE ORDER
CHANGE

PO NO: C 252857
ISSU DTE: 04/29/97 PAGE: 2
CHNG DTE: 05/02/97 REV: 2

TITLE_____ DATE_____

PLEASE RETURN ALL SIGNED DOCUMENTS WITHIN 7 DAYS OF RECEIPT TO THE PURCHASING DEPARTMENT.

NOTE: NO PAYMENTS AGAINST THIS PURCHASE ORDER WILL BE MADE UNTIL THE SIGNED DOCUMENTS ARE RETURNED.

BALANCE QUANTITY DUE: NONE
REQUIRED DELIVERY DATE: 06/06/97
ACCT: P [illegible] 1642 852 C1775 BEB197
REQUISITION/LINE: D[illegible] 0 /0001
REQUESTOR: JIM THEIS

A 2125

GRAND TOTAL $[illegible]

JOHN P. [illegible]

VENDOR

U-05663

SALES ORDER

0367

CUSTOMER ~~WILLIAM~~ FOSTER FARMS
CONTACT ~~DAVID HOWARD~~ JOHN JETTON
ADDRESS P.O BOX 457
LIVINGSTON CA 95334
TEL. No. 209 394 6905
FAX No. 209 394 6316
THEIR O/No. C 252057

ORDER DATE ~~4/1/97~~ 05/05/97
PAYMENT TERMS 33⅓/33⅓/33⅓
Q/No. Q393JA

ITEM No.	PRODUCT NAME & DESCRIPTION	No. OFF	PRICE /UNIT	TOTAL PRICE	REQUIRED DEL. DATE	ADDNL INFO
1	2 ZONE RAPID FLOW OVEN ~~(TEST KITCHEN MODEL)~~ w/ Allen Bradley components when possible	1	210,000		6-7 weeks from deposit ~~5/1/97~~	
	INCLUDES C.I.P		48,000			
	DELIVERY BUDGET $2,400					
382	INSTALLATION - 2 ENG 2 DAYS SEE ~~#0382~~		3,800			
0383	LIQUID SMOKE APP SYSTEMS SEE #0383		24,000			
				$288,200		

A 2129

U-00141

FOR OFFICE USE ONLY | INVOICE No. | NET AMOUNT | DATE

EXHIBIT 7B

THE BACK OF THIS CHECK CONTAINS AN ARTIFICIAL WATERMARK - CAN BE SEEN AT AN ANGLE

Foster Farms

FOSTER POULTRY FARMS

80-95
1012

CHECK NO
529308

PAY THE SUM 96066 DOLS 66 CTS

DATE 05/09/97

CHECK AMOUNT $96,066.66

TO THE ORDER OF
Unitherm Food Systems, Inc.
1108 W. Hartford
P.O. Box 947
Ponca City, Oklahoma 74601

Robert A. Fox

UNITED MISSOURI BANK OF CARTHAGE
CARTHAGE MISSOURI 64836

COPY

VOID AFTER 120 DAYS FROM DATE OF ISSUE

⑈529308⑈ ⑆101200958⑆ 2970094390⑈

Foster Farms

DATE	CHECK NO
05/09/97	529308
0101	167072

DATE	INVOICE/CREDIT MEMO	TYPE	DESCRIPTION	GROSS	DISCOUNT	NET
05/06/97	1919			96,066.66		96,066.66

A 2130

MAY 12 1997

THE ATTACHED CHECK IS IN PAYMENT FOR ITEMS DESCRIBED ABOVE

TOTAL

EXHIBIT 7C

UNITHERM FOOD SYSTEMS, INC.

INVOICE

1108 W. HARTFORD • P.O. Box 947 • PONCA CITY, OKLAHOMA 74602
TELEPHONE: 405-762-0197 • FAX: 405-762-0199

Nº 1919

SOLD TO

FOSTER FARMS
P. O. Box 457
Livingston, CA. 95334

SHIP TO

INVOICE DATE	PAYMENT DUE	TERMS	CUSTOMER ORDER NO.	OUR ORDER NO.	DELIVERY NOTE	SHIPPED VIA	DATE SHIPPED
5/06/97	Now	1/3-1/3-1/3	C252057	0367			

QTY. ORDERED	QTY. SHIPPED	DESCRIPTION	UNIT COST	AMOUNT
1		2-Zone Raplidflow	210,000.	
		Includes C.I.P.	48,000.	
		Installation - 2 Engineers 2 Days	3,600.	
		Liquid Smoke Apo. System	24,000.	
		Budget Delivery	2,400.	
				288,200.
		33 1/3 Down		96,066.66

A 2132

U-00144

SUB TOTAL	96,066.66
FREIGHT	
TAX	
TOTAL DUE	96,066.66

PLEASE PAY FROM INVOICE, NO STATEMENT WILL BE SENT

ALL OUTSTANDING BALANCES WILL BE CHARGED WITH A 1 ½% INTEREST PER MONTH.

WHITE COPY - CUSTOMER YELLOW COPY - ACCOUNTS PINK COPY - FILE

EXHIBIT 7D

FAX

Foster Farms
PO Box 457
1333 Swan St.
Livingston, CA 95334

Date September 24, 2001

Number of pages including cover sheet 18

From: Lorraine J. Tash
Purchasing Department
TASHL@fosterfarms.com
Phone 209-394-6996
Fax Phone 209-394-6316

UNITHERM FOOD SYSTEMS, INC
ATTN: DAVID HOWARD
Phone 916-367-0197
Fax Phone 916-367-5440
CC:

REMARKS

☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

RE: PO# 4500204439 (2nd Version)

Please sign and return at your earliest convenience.

Thank you very much,

Lorraine

EXHIBIT 8

11/20/2003 12:14 FAX 9163675440 UNITHERM

Foster P ultry Farms

Purchase rder

PO number/date
4500204439 / 08/28/2001
Contact person/Telephone
SEAN RULE/209-394-6970
Total Amount
1,411,300.00
Your vendor number with us
421046
Our fax number
209-394-6316
Our reference
Gary Ades/DH
Your person responsible
David Howard

UNITHERM FOOD SYSTEMS INC
502 INDUSTRIAL RD
BRISTOW OK 74010

Please deliver to:

TURLOCK TURKEY PLANT 2
GATE 18, 8TH STREET
TURLOCK CA 95380

Currency USD

THIS AGREEMENT dated as of August 29, 2001, between and among FOSTER POULTRY FARMS, (hereinafter "Buyer"), a corporation organized and existing under the laws of the State of California, with its principal place of business at 1000 Davis Street, Livingston, California 95334, and Unitherm Food Systems, Inc.("Seller") with a place of business at Industrial Road, Bristow, Oklahoma 74010;

The Seller shall furnish all the equipment, labor, material and services necessary to fully assemble and deliver to Buyer two (2) Post pasteurization units which will pasteurize repackaged turkey products to reduce the chances of contamination of product due to Listeria, E-coli, and other food-borne bacteria (hereinafter the "Equipment"). In addition, Seller shall provide to the Buyer all associated manuals, procedures, instructions and other data required for the operation and repair of Equipment.

Food Safety:
The Equipment will reduce the chance of product contamination and allow the Buyer to meet its customer needs. The Buyer's current customers require that these types of products be post processing pasteurized.

I. Specifications

The following specifications for the Equipment were provided by the

Foster Poultry Farms

UNITHERM FOOD SYSTEMS INC
502 INDUSTRIAL RD
BRISTOW OK 74010

PO number/date 1500204439 / 08/28/2001
Page 2

Seller. The Seller acknowledges that the Performance guarantees listed in Section II will supercede those of the following specifications if discrepancies or issues arise because of differences in the two sections.

Pasteurizer

-Material of Construction: Stainless steel grade 304 and food-quality polymers. All electrics are to be housed in Nema 4X enclosures.
-Belt Width: 80"
-Infeed Width: 80"
-Infeed Height: 41"
-Water Capacity: 1,000 gallons
-Submerged Length: 10'
-Pump Circuit: 550 gallons per minute full circulation, indirect steam injection, 3 bar dry saturated 1,500 lbs. per hour
-Drive System: Variable-speed inverter
-Service Connections: Steam - 1,500 lbs. per hour; Electric-460/3/60 50 amp;Extraction-1,800 CFM
- Equipment is fully insulated to reduce heat load in the packaging environment. The surface area of the equipment will not exceed 60°F

Vertical Impingement Chiller

-Features: Stainless steel evaporator coils, Heavy-duty 4"-insulated stainless steel encasement, Heavy-duty stainless steel flooring with 4" insulation, Twin access doors, variable residence time, high airflow "tuned" to product requirements, Stainless steel product-conveyor belt, stainless steel control panel, Defrosting activation switch and lock in panel
-Encasement: 4"-thick, food-safe stainless steel insulated panels, Stainless steel cladding on floor, falling to a drainage outlet, access doors, Inlet discharge apertures to suit product.
-Conveyor: 16 effective belt width
-Evaporators: Four units @ 30 tons thermal duty each Stainless steel with aluminum fins
-C.I.P. System: Steam system raises cabinet temperature to 170F for 12 minutes. All controls included.
-Baffles: All stainless steel, designed to eliminate "short circuiting" of air flow removable for cleaning
-Control Panel: Stainless steel enclosure, control gear UL/FM approved, Electric variable speed controller, residence time indicator in min./sec., Temperature controller (PID)
-Service Connections: Electric-480v,3ph, 60 hz, 200 amp;Steam-40 psi @ 600 lbs. Per hour, Ammonia-120 tons.

II. Performance Guarantees

Foster Poultry Farms

UNITHERM FOOD SYSTEMS INC
502 INDUSTRIAL RD
BRISTOW OK 74010

PO number/date: 4500204439 / 08/28/2001
Page: 3

The Seller acknowledges and agrees that the performance of the Equipment is the Sellers responsibly and the Seller guarantees that the Equipment will meet or exceed the following:

The lethality rate will match the protocol established at O.S.U. So that documentation from the H.A.C.C.P plan, the data recorded from the lines and the data independently validated at O.S.U. are the same (Exhibit A, attached hereto)

1. The Equipment will fit into the current plant dimensions
-Pasteurizer Curved Seal line - 13' wide, 32' long, and 16' high;
-Pasteurizer Straight Seal line - 13' wide, 32' long, and 16 high;
- Plus additional 9 width at the chiller end on only the curved seal line.
2. The Equipment will bring the surface of the product to a minimum of 175°F within 2 minutes to a depth of 3mm. This time frame is required to minimize purge in the bag. 3. The Equipment will maintain a water temperature of 205°F uniformly throughout the entire tank.
3. The Equipment will have a minimum of a 3-log decrease in count after the process (to be verified by challenge studies).
4. The Equipment will have to chill product in-line and drop core temperatures of unit back to below 40°F within 12-15 minutes to allow for immediate boxing.
5. The Equipment will be cost effective to run with minimal consumables i.e. carbon dioxide or nitrogen for chilling of the product.
6. The Equipment will be built to withstand a poultry processing plant environment and be easily cleaned.
7. The Equipment will operate at speeds with a minimum of 50 (9 lbs) pieces per minute for the curved seal bar, and 50 (9 lbs.) pieces per minute for the straight seal bar. 8600 packaging machines.8. The Equipment will maintain a temperature across product with not more than 3°c variability from high to low surface temperature.
9. Thermal Process: hot Water
10. Purge requirement not more than 2.5% purge caused by process
11. Equipment must handle chub sized products ranging between 1.25 lbs. (approximately 3" long, 3" High, 4" wide) and 13 lbs (approximately 15" long, 10" wide, 6" high)
12. Product transfer in the Equipment from the Pastuerizer to the Air chiller will be a smooth gradual transfer. Seller guarantees that the product will not be damaged in this transfer process.
13. Product supports will be square in design and not round
14. All Equipment parts that are in contact with heat or cold will not become damaged with the changes in temperature.
15. The chillers must work 8 hours continuously before the unit requires to be defrosted. Defrost will take no more than 30 minutes
16. Proximity sensors must not be negatively affected by the chill

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process
17. All electronic controls on the Equipment will be Allen Bradley

18. Seller agrees to provide premium quality components. Prior to manufacture, all engineering drawings and components will be reviewed and approved by Foster personnel.

19. The Seller guarantees that the Buyer's end product will not be modified in any way outside of the pasteurization process(i.e. flavor, texture, and form of the product will remain the same as it was prior to pasteurization).

III. Process Flow:

The two Pasteurizers will have slightly different specifications to accommodate the differences in the individual lines. The following describes the process flows to accomplish this:

1. Curve Seal Cryovac 8600 Pasteurizer Line - All stripped product will be packaged on the 8600 in a special high temperature abuse bag and be conveyed to the post pasteurizer where it will be submerged for 90 - 150 seconds in 205°F hot water. The products will not float above the surface as they will be held down by their own weight or a mechanism of the Equipment. Product will exit the pasteurizer and immediately enter the chiller where the temperature will be dropped to below 40°F. The product will exit the chiller and then be placed into a shipping carton, sealed, dated, weighed and palletized for shipment. This 8600 has a curved seal bar and is set up in line to package product that has gone through the R.F. (Rapid Flow) and impingement process prior to packaging. The product picks up additional heat prior to going through the pasteurizer raising temperatures 135°F approximately 3/8" to 1/2" deep into the product. This will require additional chiller equipment (line item 2 on page 1 of this contract) in order to keep up with the 50 pieces per minute requirement.

2. Straight Seal Cryovac 8600 (older unit)Pasteurizer Line - This line has the straight seal bar and is used for products that are simply repackaged or are cooked open in the ovens. The heat picked up in this process is minimal and only goes approximately 1/8" deep into the product. These products will only require up to 9 minutes in the chiller to be cold enough to box.

IV. General Terms and Conditions

1. Payment Terms - The payment terms will be separate for each line, 30% down payment upon contract signing, order placement and invoice; 60% upon invoice, acceptance and completion at Seller's plant; 10% Net

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30 days upon final delivery, invoice, and the Buyers acceptance of successful installation.

2. Guaranteed Delivery Date - The Seller guarantees the delivery date. The Seller will deliver and install the equipment within 22 weeks of the placement of this purchase order. For every day that all the equipment is not delivered (delivered, installed, and in operation) by the 22nd week from order placement, a graduated penalty will be paid by the Seller to the Buyer as described in the following:

For every day that the project is not complete by the 22nd week the Seller agrees to pay the Buyer $1000.00 per day penalty;
And for every day that the project is not complete by the 24th week, the Seller agrees to pay the Buyer $2000.00 per day penalty;

and for every day that the project is not complete by the 26th week, the Seller agrees to pay the Buyer $3000.00 per day penalty;

3. If the Equipment does not perform to the performance criteria listed within this contract, the Buyer reserves the right, at the Buyers option, to return the equipment to the Seller (at the Sellers cost) for a full refund. Upon the Buyers option to return the Equipment, Seller also agrees to reimburse Buyer for any and all labor charges associated with the installation of the Equipment.

4. All equipment will be warranted for a minimum of 1 year as described in Section VI item 7 of this contract except for the Belting and surrounding assemblies which will be guaranteed not to have excessive ware and will be warranted for 2 years.

V. Installation, Freight, and Start-up

Seller will install the equipment. Installation is defined as the time and work required to physically assemble the unit, connect it to the required services, and insure its proper operation, prior to testing of the product. The Buyer will pay the Seller actual cost of $65 per hour for installation.

The out of pocket expenses of the Seller will be charged at the actual incurred costs for reimbursment by the Buyer. These will not exceed the following values:

- 6 people airfare $6,000
- 6 hotel rooms at $100/night = $8,400
- Per Diem $2,500
- Car Rental $1,400

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Total expenses $18,300

Start-up will include the time required to operate and train the Buyers employees on the equipment with the test product. The Buyer will pay the Seller actual costs of $85 per hour for start-up.

The total Installation, Start-up, and Expenses (including all costs, labor, expenses, and travel) will be charged at the actual rates but at no time will they exceed $68,300 together. Freight will will be charged at the actual cost. According to the Seller this will require three delivery trucks and is estimated to be $6000, but at no time will freight exceed $8,000

3. Installation of Plumbing and Refrigeration will not be supplied by the Seller.

VI. Foster Farms Discrete Purchase Order Terms and Conditions Applicable for Goods and Services

1. Seller shall, at its own expense, and assuming all risks in any way connected therewith, perform work for Buyer, and shall furnish all labor, equipment and materials required in strict compliance with all provisions of this Purchase Order.

2. Seller shall commence performance of the work when directed by Buyer and shall complete the same as expeditiously as practicable and, in any event, within the time specified in the Purchase Order.

3. Seller shall submit insurance certificates to the attention of Buyers Purchasing Department referencing the Purchase Order number prior to commencement of work or site mobilization.

4. Seller is an independent contractor, and all persons employed by Seller in connection herewith shall be its employees and not employees of Buyer in any respect.

5. Seller hereby releases and shall indemnify, defend and hold harmless Buyer, and its subsidiaries and affiliates and the officers, agents, employees, and authorized representatives of all the foregoing from and against any and all suits, actions, legal or administrative proceedings, claims, demands, damages, liabilities, interest, attorney's fees, costs and expenses of whatsoever kind or nature whether arising before or after completion of the work hereunder and in any manner directly or indirectly caused, occasioned, or contributed to in whole or in part, or claimed to be caused, occasioned, or contributed to in whole or in part, by reason of any act, omission, fault or negligence whether active or passive of Seller, its

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subcontractors or of anyone acting under its direction or control or on its behalf in connection with or incidental to the performance of this Purchase Order. Seller's aforesaid release, indemnity and hold harmless obligations, or portions or applications thereof, shall apply even in the event of fault or negligence of the parties released to fullest extent permitted by law, but in no event shall they apply to liability caused by the willful misconduct of the party released, indemnified or held harmless.

6. The Seller shall, at its sole expense, maintain in effect at all times during the performance of the services insurance coverage with limits not less than those set forth below and under forms of policies with insurers satisfactory to Buyer.

Coverage
Minimum Amounts and Limits
(a) Worker's Compensation Statutory Requirements at Location of Work
(b) Comprehensive General Liability $2,000,000 Each Occurrence
(c) Automobile Liability $1,000,000 Single Limit

Coverage (b) shall apply to the indemnity agreement in paragraph 5 above and shall include Buyers officers and employees, each as additional insured but only in regard to their liability arising out of Seller's performance of the work or out of operations performed by others on behalf of Seller under this Purchase Order. The insurance as afforded to such additional insured's shall state that it is primary insurance and shall provide for a severability of interest or cross-liability clause. Prior to commencing performance of any work or site mobilization, Seller shall furnish Buyer with certificates of insurance (identifying on the face thereof the work to be performed and Purchase Order number as evidence of the above required insurance and such certificates shall provide for thirty (30) days written notice to Buyer prior to cancellation thereof.

Buyer is not maintaining any insurance on behalf of Seller covering loss or damage to the work or to any other property of Seller unless otherwise specifically set forth herein.

None of the requirements contained herein as to types, limits, and approval of insurance coverage to be maintained by Seller are intended to and shall not in any manner limit or quantify the liabilities and obligations assumed by Seller under this Purchase Order.

Notices, in original and one copy of cancellation, termination and alteration of such policies shall be delivered to the Buyers Purchasing Department.

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7. All materials and equipment shall be new, and workmanship shall be first class in every respect. The work shall be subject to inspection and acceptance by Buyer. Seller shall guarantee its work hereunder for a period of 12 months after completion and acceptance of the work unless otherwise set forth herein. In the event Buyer discovers defects in material or workmanship at any time before the expiration of the specified warranty period, Seller shall, upon written notice from Buyer, repair or replace at its sole expense any such defects. Buyer may perform such repairs or replacements by other reasonable means and Seller agrees to pay for such corrective measures. Neither acceptance of the work by Buyer nor payment shall relieve Seller from liability under the indemnity clause or any of the guarantees or warranties contained or implied herein.

8. FDA , USDA, State and Local Requirements - All equipment or material that will be used in a food production environment must comply with all Food and Drug Administration, United States Department of Agriculture, State, Local or Municipal laws, requirements and regulations. Seller warrants that it will have complied with all applicable governmental laws, regulations and orders, including the Fair Labor Standards Act of 1938, as amended, in connection with all Products delivered under this Agreement. All such warranties shall survive termination of this Agreement.

9. Seller shall comply with Buyers job-site procedures and regulations and with all applicable local, State and Federal laws, rules and regulations and shall obtain all permits required for any of the work performed hereunder. Seller shall procure and pay for all permits and inspections required for any of the work performed hereunder and shall furnish any bonds, security or deposits required to perform the work.

10. For work performed on Buyer premises, Seller shall strictly observe Buyer work rules and security requirements. All work shall be carried out during normal Buyer working hours unless specifically agreed to in writing by Buyer. Seller shall, at Buyers request, discharge any incompetent, dishonest, or uncooperative employee(s).

11. Buyer may, at any time, direct in writing additions, deletions or changes to all or any part of the work, and Seller agrees to perform such work as changed. If any such change causes an increase or decrease in the cost of or in the time required performing such work, Seller shall submit detail information substantiating such claims. If required, an equitable adjustment shall be made to the price or time of performance, or both, and the Purchase Order shall be modified accordingly.

12. Seller shall promptly pay all claims of persons or firms furnishing

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labor, equipment or materials used in performing the work hereunder. Buyer may require Seller to submit satisfactory evidence of payment and releases of all such claims. If there is any evidence of any such unpaid claim, Buyer may withhold any payment until Seller has furnished such evidence of payment and release and shall indemnify and defend Buyer against any liability or loss arising from any such claim.

13. Any assignment by Seller of this Purchase Order or of any rights hereunder in any manner, in whole or in part, by operation of law or otherwise, without the prior written consent of Buyer shall be void.

14. Seller shall at all times conduct all operations under the Purchase Order in a manner to avoid risks of bodily harm to persons, damage to any property and fire. Seller shall be solely responsible to take all precautions necessary and continuously inspect all work, materials, and equipment to discover, determine and correct any such conditions which may result in any of the aforementioned risks. All Seller personnel, while on Buyer Property, are required to wear the following protective equipment: hard hats, safety glasses, work shoes, and other appropriate protective equipment. The Buyer will have the right to halt work due to unsafe working conditions. The Seller is responsible for job-site safety and is to isolate the construction area with fencing or barricades, as required. A pre-construction safety meeting is to be held with the Buyer, as required.

15. Buyer will not be responsible for goods delivered or services rendered without a valid Purchase Order. No substitution of goods and/or services from those specified will be accepted without the prior written consent of Buyer in the form of a revised Purchase Order. Neither this Purchase Order nor any interest therein or claim arising hereunder may be assigned or transferred by the Seller of this Purchase Order without the prior written consent of Buyer.

16. The Seller must notify Buyer if unable to ship goods and/or render services specified on or before the date specified on the Purchase Order. The date of delivery and/or performance stated on the Purchase Order is a material part of the Sellers acceptance of this Purchase Order; Buyers acceptance of goods and/or performance after said date is solely optional with Buyer and, if accepted, is subject to a reasonabl price reduction, exercised unilaterally by Buyer, unless otherwise agreed in writing by Buyer. Where the Purchase Order specifies, or Buyer otherwise permits partial shipments, and where billing for a partial shipment under on Purchase Order is rendered, it is understood that Sellers invoice dating will be extended to the final receipt of all goods by Buyer. Goods must not be shipped C.O.D. Buyer shall have no risk of loss with respect to goods ordered until actually delivered and receipted for by Buyer, and Seller shall adequately insure all

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goods from all insurable perils during transit. All shipments are to be F.O.B. destination unless otherwise indicated on the Purchase Order.

17. The price or prices specified on the Purchase Order are firm and are not subject to increase of any kind without the prior written consent of Buyer. Cash discounts specified on the Purchase Order, or otherwise granted by Seller in general practice, shall be taken by Buyer, unless otherwise specifically stated on the Purchase Order. No charge shall be made to Buyer for packing, boxing, handling, shipping, or cartage, unless specified on the Purchase Order or otherwise specifically authorized in advance by Buyer. Charges, if any, for returnable containers, reels, or drums must be separately itemized on Sellers invoices.

18. By acceptance of this Purchase Order, Seller warrants to and for the benefit of Buyer (a) that all goods delivered will be of good quality and free from all defects of every kind and nature, (b) that all services rendered will be promptly and diligently performed in a good and workmanlike manner, (c) that all goods delivered shall be proper and suitable for the intended purpose of Buyer, whether specifically stated on the Purchase Order, apparent by reasonable circumstances, or otherwise known to Seller, (d) that all goods delivered are validly owned by Seller and are delivered to Buyer free from all liens, encumbrances, and claims of others of every kind and nature, (3) that all goods delivered shall be in strict conformance with samples, descriptions, brochures, specifications, and oral assurances provided by Seller to Buyer in submitting this Purchase Order, (f) that all goods delivered are absolutely free from infringement of any patent, copyright trademark, tradename, a brand or slogan, and are not being sold in unfair competition, restraint of trade, or in violation of any other commercial law, rule, or regulation (g) that all goods delivered are in full compliance with the Occupational Safety and Health Act of 1970 (OSHA) and the California General Industry Safety Orders, and all standards and regulation issued under such laws, (h) that all goods delivered have been produced and delivered and/or services rendered have been performed, and all aspects of Sellers business are in compliance with all relevant equal employment laws, rules, and regulations, including, but without limitation, the Equal Employment Opportunity clause, Chapter 60, Title 41, Code of Federal Regulations, applicable to Government Sellers, and subcontractors. (i) that Seller by acceptance of this Purchase Order, agrees to indemnify, save and hold Buyer, its successors and assigns, free and harmless from any and all defaults, breaches, or failures or warranties hereinabove set forth, including, but without limitation, all claims of others, whether or not well founded, and including all costs of suit, defense, or other action including reasonable attorneys fees.

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19. All goods delivered shall be subject to the inspection and trial use by Buyer, and may be returned to Seller, after such trial use, if such goods do not perform to Buyers complete satisfaction.

20. Confidentiality: In the event that Seller obtains, in the course of Sellers performance hereunder, knowledge of any trade secrets or other information of a confidential nature of Buyer, Seller agrees that Seller (and Sellers agents and employees) shall not disclose such trade secrets or confidential information to others, and shall not use such trade secrets for its own accounts or for the purposes of any third party.

21. Unless this Purchase Order is signed by an officer of Buyer, the Purchase Order is conditional upon being within the authority conferred upon the signing representative by the Board of Directors of Buyer.

VII. Foster Farms Discrete Purchase Order Terms and Conditions Applicable for Goods

1. Buyer will not be responsible for goods delivered or services rendered without a valid Purchase Order. No substitution of goods and/or services from those specified will be accepted without the prior written consent of Buyer in the form of a revised Purchase Order. Neither this Purchase Order nor any interest therein or claim arising hereunder may be assigned or transferred by the Seller of this Purchase Order without the prior written consent of Buyer.

2. The Seller must notify Buyer if unable to ship goods and/or render services specified on or before the date specified on the Purchase Order. The date of delivery and/or performance stated on the Purchase Order is a material part of the Sellers acceptance of this Purchase Order; Buyers acceptance of goods and/or performance after said date is solely optional with Buyer and, if accepted, is subject to a reasonable price reduction, exercised unilaterally by Buyer, unless otherwise agreed in writing by Buyer. Where the Purchase Order specifies, or Buyer otherwise permits partial shipments, and where billing for a partial shipment under on Purchase Order is rendered, it is understood that Sellers invoice dating will be extended to the final receipt of all goods by Buyer. Goods must not be shipped C.O.D. Buyer shall have no risk of loss with respect to goods ordered until actually delivered and receipted for by Buyer, and Seller shall adequately insure all goods from all insurable perils during transit. All shipments are to be F.O.B. destination unless otherwise indicated on the Purchase Order.

3. The price or prices specified on the Purchase Order are firm and are not subject to increase of any kind without the prior written

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consent of Buyer. Cash discounts specified on the Purchase Order, or otherwise granted by Seller in general practice, shall be taken by Buyer, unless otherwise specifically stated on the Purchase Order. No charge shall be made to Buyer for packing, boxing, handling, shipping, or cartage, unless specified on the Purchase Order or otherwise specifically authorized in advance by Buyer. Charges, if any, for returnable containers, reels, or drums must be separately itemized on Sellers invoices.

4. By acceptance of this Purchase Order, Seller warrants to and for the benefit of Buyer (a) that all goods delivered will be of good quality and free from all defects of every kind and nature, (b) that all services rendered will be promptly and diligently performed in a good and workmanlike manner, (c) that all goods delivered shall be proper and suitable for the intended purpose of Buyer, whether specifically stated on the Purchase Order, apparent by reasonable circumstances, or otherwise known to Seller, (d) that all goods delivered are validly owned by Seller and are delivered to Buyer free from all liens, encumbrances, and claims of others of every kind and nature, (e) that all goods delivered shall be in strict conformance with samples, descriptions, brochures, specifications, and oral assurances provided by Seller to Buyer in submitting this Purchase Order, (f) that all goods delivered are absolutely free from infringement of any patent, copyright trademark, tradename, a brand or slogan, and are not being sold in unfair competition, restraint of trade, or in violation of any other commercial law, rule, or regulation (g) that all goods delivered are in full compliance with the Occupational Safety and Health Act of 1970 (OSHA) and the California General Industry Safety Orders, and all standards and regulation issued under such laws, (h) that all goods delivered have been produced and delivered and/or services rendered have been performed, and all aspects of Sellers business are in compliance with all relevant equal employment laws, rules, and regulations, including, but without limitation, the Equal Employment Opportunity clause, Chapter 60, Title 41, Code of Federal Regulations, applicable to Government Sellers, and subcontractors, (i) that Seller by acceptance of this Purchase Order, agrees to indemnify, save and hold Buyer, its successors and assigns, free and harmless from any and all defaults, breaches, or failures or warranties hereinabove set forth, including, but without limitation, all claims of others, whether or not well founded, and including all costs of suit, defense, or other action including reasonable attorneys fees.

5. If this Purchase Order covers a contract or subcontract, the Seller and subcontractor shall indemnify and hold harmless Buyer and/or its vendee from and against any and all claims, actions, causes of action

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and liability or on account of injury to or the death of any person or persons and damage to property (including property of Seller) in any manner caused by, contributed to, or arising out of the performance by the subcontractor of the work covered by such subcontract, including, but without limiting the generality of the foregoing, claims, actions, causes of action, and liability to which the negligence of Seller is or is alleged to have been the sole or a contributing cause.

6. FDA , USDA, State and Local Requirements - All equipment or material that will be used in a food production environment must comply with all Food and Drug Administration, United States Department of Agriculture, State, Local or Municipal laws, requirements and regulations. Seller warrants that it will have complied with all applicable governmental laws, regulations and orders, including the Fair Labor Standards Act of 1938, as amended, in connection with all Products delivered under this Agreement. All such warranties shall survive termination of this Agreement.

7. All goods delivered shall be subject to the inspection and trial use by Buyer, and may be returned for a full refund (includes but is not limited to all freight, labor, and equipment) to Seller, after such trial use, if such goods do not perform to Buyers complete satisfaction.

8. Confidentiality: In the event that Seller obtains, in the course of Sellers performance hereunder, knowledge of any trade secrets or other information of a confidential nature of Buyer, Seller agrees that Seller (and Sellers agents and employees) shall not disclose such trade secrets or confidential information to others, and shall not use such trade secrets for its own accounts or for the purposes of any third party.

9. Please send invoices to:

Accounts Payable,
P.O. Box 457,
Livingston, CA 95334

10. Unless this Purchase Order is signed by an officer of Buyer, the Purchase Order is conditional upon being within the authority conferred upon the signing representative by the Board of Directors of Buyer.

Item	Order qty.	Unit	Material Description	Price per unit	Net value

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Item	Order qty.	Unit	Material Description	Price per unit	Net value
00001	2	each	PASTURIZER W/ CHILLER	550,000.00	1,100,000.00
	(One for each packaging line)				
	Deliv. date 01/30/2002				
00002	1	each	ADDITIONAL CHILLER	235,000.00	235,000.00
	(For curved seal 8600 line as described)				
	Deliv. date 01/30/2002				
00003	1	each	INSTALLATION AND TRAINING	68,300.00	68,300.00
	Deliv. date 01/30/2002				
00004	1	each	FREIGHT	8,000.00	8,000.00
	Deliv. date 01/30/2002				

Tot. net item val. excl. tax USD 1,411,300.00

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I acknowledge receipt and acceptance of this contract and I am authorized by the Board of Directors of my respective company to sign this contract.

For the Seller

Signed: [signature]

Title: President

Date: Sept 25th, 2001

For the Buyer

Signed: _____

Title: _____

Date: _____

Signed: _____

Title: _____

Date: _____

Signed: _____

Title: _____

Date: _____

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TOTAL P.16

SALES ORDER

№ 1493

CUSTOMER Foster Farms
CONTACT Phil Green
ADDRESS 1333 Swan St.
Livingston CA 95334
TEL. No 209-394-7901
FAX No " " 6316
THEIR O/No 4500204439

ORDER DATE 9.25.01
PAYMENT TERMS
Q/No.

ITEM No.	PRODUCT NAME & DESCRIPTION	No.	PRICE /UNIT	TOTAL PRICE	REQUIRED DEL. DATE
	Pasteurizer w/Chiller	2	550,000	1,100,000	1/30/02
	Add'l Chiller	1	235.000	235.000	
	Installation & Training	1	68,300	68300	
	Freight	1	8.000	8,000	

EXHIBIT 9

As Printing

FOR OFFICE USE ONLY | INVOICE No. | NET AMOUNT | DATE

UNITHERM FOOD SYSTEMS, INC.
502 Industrial Road
Bristow, Oklahoma 74010

Tel: 918-367-0197
Fax: 918-367-5440
E-mail: unitherm@unithermfoodsystems.com

COOK / CHILL SPECIALISTS

FAX TRANSMITTAL

Date: October 1, 2001

To: Phil Green
Shawn Pliska
Foster Farms

Fax #: 209-394-6316

From: David Howard

# of Pages: 1

We acknowledge that you have put a hold or cancelled the pasteurization contract due to a change in your company's business strategies.

I hope that things improve speedily for Foster Farms.

Yours sincerely,

EXHIBIT 10

UNITHERM FOOD SYSTEMS, INC.
502 Industrial Road
Bristow, Oklahoma 74010

Tel: 918-367-0197
Fax: 918-367-5440
E-mail: unitherm@unithermfoodsystems.com

COOK / CHILL SPECIALISTS

December 9, 2002

FAXED 12-9-02

All contents are Confidential and considered Trade Secrets of Unitherm

Jay Jandrain
CAROLINA TURKEYS

Q1553DH

Via Emial: jjandrain@carolinaturkeys.com

Dear Jay,

The current position on pasteurization is to achieve a 4-log reduction in listeria whilst not creating a purge problem. This can be achieved by accelerating the process using the Infrared system or linear oven and then pasteurizing in water for 60 seconds. There is data available on this from Dr. Peter Muriana at O.S.U. His telephone number is 405-744-5563.

I enclose a typical layout for a system size at 55 pieces per minute.

The chill time is typically 12 minutes at -40°F.

Budget prices are: $950,000 for the combination system
$750,000 for a pasteurization line without the Infrared

If you intend to chill the product after exiting the Impingement Oven and Pasteurizer combined, the chill time will be 35 minutes. This is because the energy delivered from the oven is more than the Infrared System. This would increase your cost to $935,000.

If you have any further questions, feel free to contact me anytime.

Yours sincerely,

David Howard
President

EXHIBIT 11

Visit our web site at www.unithermfoodsystems.com

UNITHERM FOOD SYSTEMS, INC.
502 Industrial Road
Bristow, Oklahoma 74010

Tel: 918-367-0197
Fax: 918-367-5440
E-mail: unitherm@unithermfoodsystems.com

COOK / CHILL SPECIALISTS

E-MAILED 12-20-02

December 20, 2002

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Jay Jandrain
CAROLINA TURKEYS

Q1557DH

Via Email: jjandrain@carolinaturkeys.com

Dear Jay,

Attached is the drawing for 65 pieces per minute. I mentioned earlier, we can segregate product from two 8600. The price of the system is as follows:

(2) Twin I.R. Pasteurizers	$125,000 each
(1) Aquaflow Pasteurizer and Chiller	$850,000
Budget for Installation:	$ 50,000
Budget for delivery:	$ 20,000

If you would like to see a system, let me know.

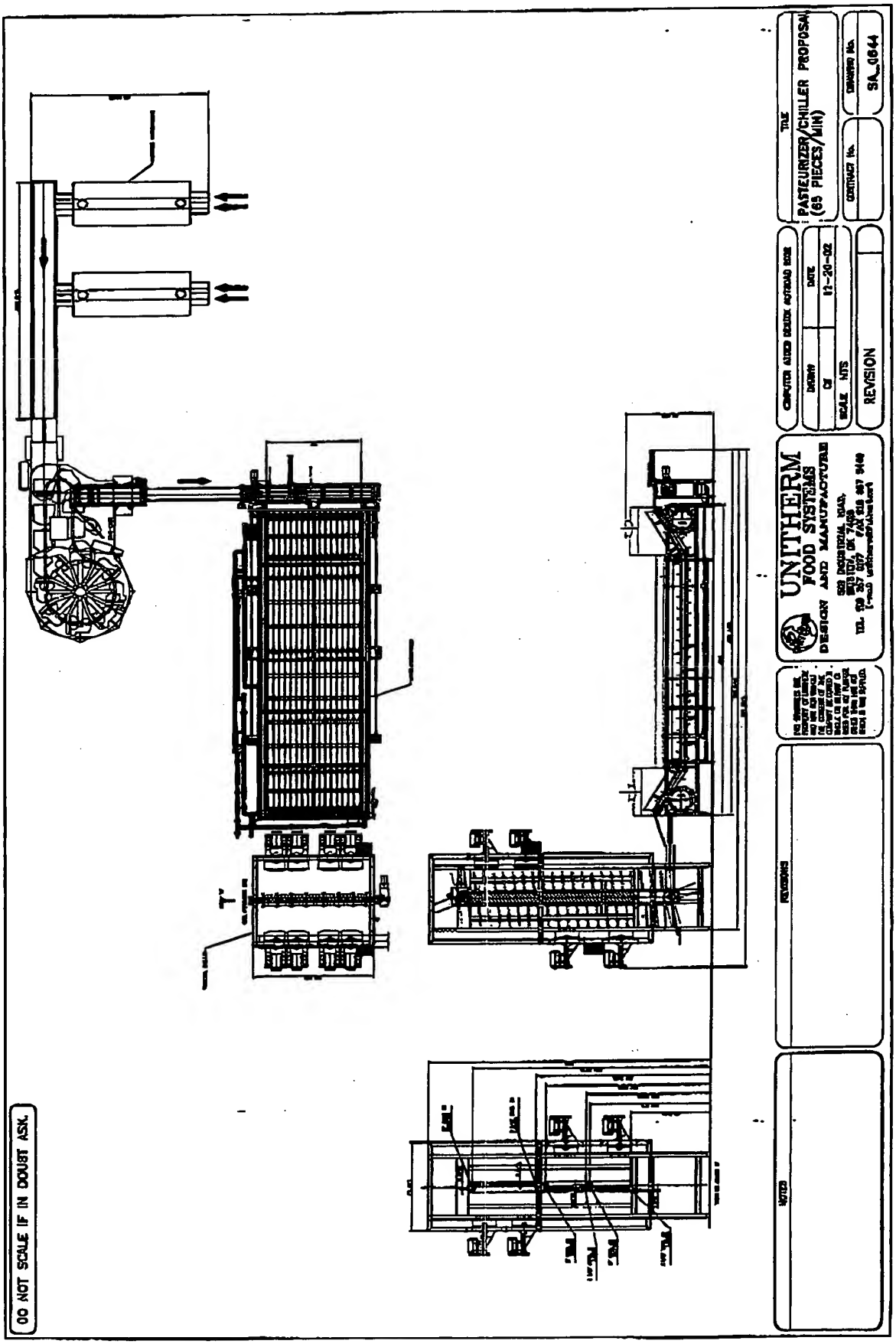
Best Regards,

David Howard
President

DH/cm

EXHIBIT 12

Visit our web site at www.unithermfoodsystems.com


PASTEURIZER/CHILLER PROPOSAL
(65 PIECES/MIN)
SA_0644
REVISION
UNITHERM
FOOD SYSTEMS
DESIGN AND MANUFACTURE
DO NOT SCALE IF IN DOUBT ASK.

UNITHERM FOOD SYSTEMS INC.
502 Industrial Road
Bristow, Oklahoma 74010

Tel: 918-367-0197
Fax: 918-367-5440
E-MAIL: unitherm@unithermfoodsystems.com

COOK / CHILL SPECIALISTS

CONFIDENTIALITY AGREEMENT

This Confidentiality Agreement ("Agreement") will confirm our mutual understanding in connection with UNITTHERM FOOD SYSTEMS, Inc. ("The Company") providing, and your receipt of, information regarding The Company.

1. Information means all oral or written data, reports, records or materials ("Information") obtained from The Company, including the knowledge that The Company may be considering a sale, or even the fact that Information has been provided. Information shall not include, and all obligations as to non-disclosure by the undersigned shall cease to any part of, such Information to the extent that such Information: (i) is or becomes public other than as a result of acts by the undersigned; (ii) can be shown was already known to the undersigned at the time of its disclosure hereunder; (iii) is independently obtained by the undersigned from a third party having no duty of confidentiality to The Company; (iv) is independently developed by the undersigned without use of any Information supplied hereunder; or (v) is obligated to be disclosed pursuant to applicable law, regulation or legal process.

2. Information is being furnished solely in connection with your consideration of the acquisition of The Company and shall be treated as "secret" and "confidential" and no portion of it shall be disclosed to others, except to those of your employees and agents whose knowledge of the Information is required for you to evaluate The Company as a potential acquisition and who shall assume the same obligations as you under this Agreement. The undersigned hereby assumes full responsibility for the compliance of such employees or agents to the terms of this Agreement.

   The undersigned further agrees that it will not interfere with any business of The Company through the use of any Information or knowledge acquired under this Agreement nor use any such Information for its own account.

3. All Information shall be promptly returned or destroyed, as directed by The Company.

EXHIBIT 13

Page 2

4. It is understood that (a) no representations or warranties are being made as to the completeness or accuracy of any Information and (b) any and all representations and warranties shall be made solely by The Company in a signed acquisition agreement or purchase contract and then be subject to the provisions thereof.

5. The undersigned acknowledges the responsibility to perform a due diligence review at its own cost and expense prior to acquisition.

6. The respective obligations of the parties under this Agreement shall survive for a period of three years following the date hereof.

Name (please print): P Hinderaker Title: President

Company: Alkar Rapid Pak, Inc

Address: ______________________ Tel: ______________

Lodi WI 53704 Fax: ______________

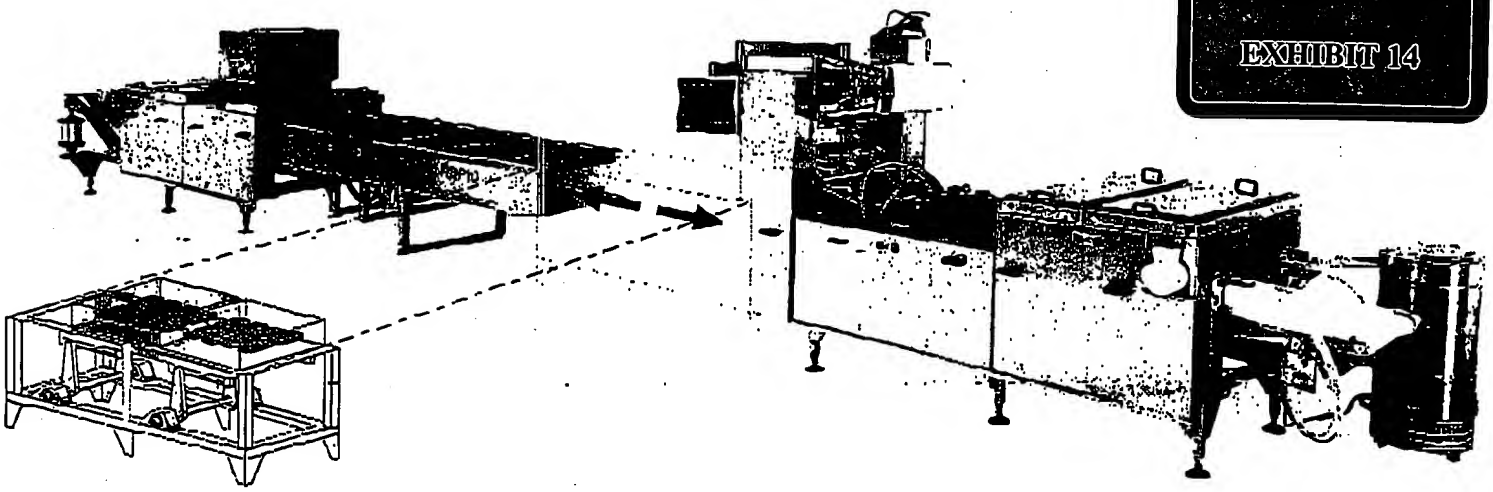
(City, State, Zip)

Email: ______________

Signature: [signature] Date: 5/1/03

Unitherm Food Systems, Inc.. 502 Industrial Road, Bristow, OK 74010
Phone: 918-367-0197 Fax: 918-367-5440
Email: Unitherm@unithermfoodsystems.com

EXHIBIT 14



RAPIDPAK FLASH PASTEURIZATION

- 4 log reduction for Lm indicator organism
- Maintains current line speeds
- No effect on product sensory characteristics
- Purge minimized
- No formulation change required
- Minimal floorspace impact
- Dry package maintains index pattern for labeling
- Low capital cost, very low cost per package
- Standard RP-55 can be retrofit with SSP module

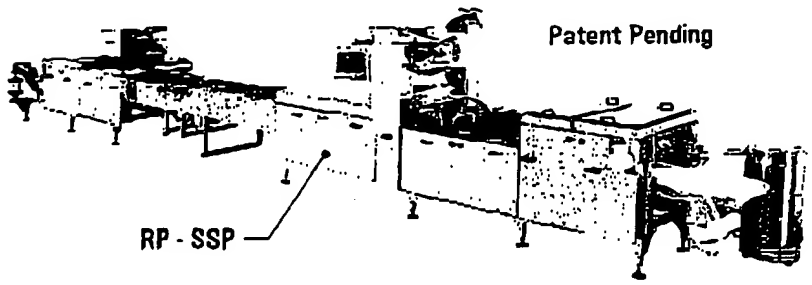
Development Partners

ALKAR — Pasteurization expertise

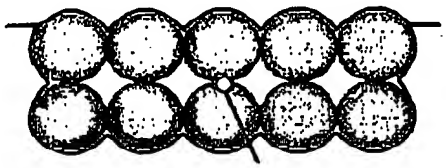
RapidPak — Packaging machine design

Oscar Mayer — Lab & Pilot plant testing facilities

USDA — Original steam-vacuum research



Patent Pending



- Conventional hot water pasteurization recooks product 20-30 minutes plus cooling time to be effective
- RP-SSP solves all the problems of conventional surface pasteurization

PURE & SIMPLE

RapidPak ALKAR-RapidPak, Inc. • P.O. Box 260 • Lodi, Wisconsin 53555 USA • Phone: 608/592-3211 • Fax: 608/592-4039 • www.rapidpak.com

FOLEY & LARDNER
ATTORNEYS AT LAW

FOLEY & LARDNER
VEREX PLAZA
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POST OFFICE BOX 1497
MADISON, WISCONSIN 53701-1497
608.257.5035 TEL
608.258.4258 FAX
www.foleylardner.com

WRITER'S DIRECT LINE
608.258.4268
rabeggien@foleylaw.com EMAIL

CLIENT/MATTER NUMBER
038702-0115

July 1, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David Howard
Unitherm Food Systems, Inc.
502 Industrial Road
Bristow, OK 74010

Re: ALKAR-RapidPak, Inc.
Our Ref. No.: 038702-0115

Dear Mr. Howard:

We represent ALKAR-RapidPak, Inc. in regards to intellectual property matters. It has come to our attention that you are asserting patent rights with respect to pasteurization technology in letters to prospective and current customers of our client. It appears that the letters are meant to coerce these customers of our client to purchase equipment from Unitherm Food Systems, Inc. instead of purchasing equipment from ALKAR-RapidPak, Inc.

In the meantime, we trust you will avoid making any false or misleading statements, and correct any false or misleading statements that may have already been made, in regards to intellectual property rights that could damage the business relationships of ALKAR-RapidPak, Inc. Please also take care to avoid any other actions that could unfairly or unlawfully damage our client's current and prospective business relationships.

We have searched for, but have not found, any issued U.S. patents or published U.S. patent applications owned by Unitherm Food Systems, Inc. that would give rise to valid patent rights in the United States. ALKAR-RapidPak, Inc. seeks to respect the intellectual property of others, and will take prudent steps to avoid infringing any valid intellectual property right of Unitherm Food Systems, Inc. In this regard, we ask you to provide us with information that will allow us to evaluate the scope of any rights Unitherm Food Systems, Inc. may have. In particular, please provide the patent number of any issued U.S. patent, or the publication number of any published U.S. patent application, giving rise to valid patent rights in the United States that can be asserted by Unitherm Food Systems, Inc. If you believe that an unpublished U.S. patent application gives rise to valid patent rights in the United States that can be asserted by Unitherm Food Systems, Inc., please provide us with a copy of the file history for any such application, including the application itself and any correspondence with the U.S. Patent and Trademark Office.

EXHIBIT 15

FOLEY & LARDNER
ATTORNEYS AT LAW

Please direct any further correspondence in this matter to m . We look forward to your prompt response.

Very truly yours,

Rick L. Abegglen

cc: Mr. Phil Hinderaker

FOLEY & LARDNER
ATTORNEYS AT LAW

FOLEY & LARDNER
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150 EAST GILMAN STREET
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608.258.4258 FAX
www.foleylardner.com

WRITER'S DIRECT LINE
608.258.4268
rabegglen@foleylaw.com EMAIL

CLIENT/MATTER NUMBER
038702-0115

July 30, 2003

VIA FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis D. Brown, Esq.
Fellers, Snider, Blankenship, Bailey, & Tippens, P.C.
The Kennedy Building
321 South Boston, Suite 800
Tulsa, OK 74103-3318

EXHIBIT 16

Re: Unitherm Food Systems, Inc.
Our Ref. No.: 038702-0115

Dear Mr. Brown:

We are in receipt of your letter of July 18, 2003 regarding Unitherm's assertion of patent rights with respect to pasteurization technology in letters to prospective and current customers of our client, ALKAR-Rapidpak, Inc. ("ALKAR").

Initially, we note that your letter of July 18, 2003 states that "Contrary to the allegations in your letter we are confident that your client, ALKAR, fully understands that Unitherm has not asserted that it has yet obtained any patents pertaining to its pasteurization technology." However, the enclosed letter dated May 12, 2003 from David Howard to Tim McConnell at Foster Farms offers to license technology for which patent applications are pending, and states that those patent applications include allowed claims. That letter to Foster Farms also included as an attachment a letter dated May 12, 2003 from you to David Howard, in which you describe the scope of the pending claims of that application. Mr. Howard's May 12, 2003 letter to Foster Farms, and other correspondence Mr. Howard has sent to other customers of ALKAR, show that Unitherm is asserting licensable rights under their pending patent applications, even if Unitherm has not asserted that it has obtained any "issued patents."

It still appears to us that the letters Unitherm has sent to prospective and current customers of ALKAR are meant to coerce those customers to purchase equipment from Unitherm instead of purchasing equipment from ALKAR. Please be advised that Unitherm's actions are in fact damaging and interfering with the business relationships between ALKAR and its customers, including but not limited to Carolina Turkeys.

Further, we note that your letter of July 18, 2003 states that "Unitherm has been very responsive to specific customer questions concerning the subject matter and ongoing scope of its pending patent applications." As you know, on July 1, 2003 we sent a letter to David Howard of Unitherm, requesting that Unitherm provide us with information that would allow us to evaluate the

BRUSSELS
CHICAGO
DENVER
DETROIT
JACKSONVILLE
LOS ANGELES
MADISON
MILWAUKEE
ORLANDO
SACRAMENTO
SAN DIEGO
SAN DIEGO/DEL MAR
SAN FRANCISCO
TALLAHASSEE
TAMPA
WASHINGTON, D.C.
WEST PALM BEACH

RECEIVED AUG 0 4 2003

scope of any patent rights Unitherm may have, but your July 18, 2003 response to that letter did not provide us with any such information. I have also confirmed today that Foster Farms has not received any response whatsoever to its letter dated June 12, 2003 to David Howard requesting information concerning the subject matter and ongoing scope of Unitherm's pending patent applications. Thus, contrary to the statement in your letter of July 18, 2003, in fact Unitherm has been completely unresponsive to inquiries from ALKAR and Foster Farms concerning the subject matter and ongoing scope of Unitherm's pending patent applications.

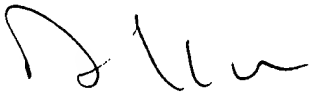
Your letter of July 18, 2003 states that "Unitherm is committed to ethical conduct and fair dealing." As you know, the basic premise of the patent system in the United States is that inventors will make a full disclosure of their inventions in exchange for exclusive rights to their inventions for a limited time. Unitherm is asserting rights under their patent applications without making any disclosure, and it is this practice which we believe is fundamentally unfair. If Unitherm wants to compete fairly, Unitherm should make the required disclosure before asserting patent rights and interfering with ALKAR's business. If Unitherm is truly committed to ethical conduct and fair dealing, please provide us with the filing date and prosecution history of Unitherm's pending patent applications so we may evaluate the scope of any patent rights Unitherm may have.

Our client is committed to ethical conduct and fair dealing, as Unitherm claims to be, and in that regard we wish to help Unitherm comply with its duty of disclosure to the Patent Office in connection with its pending patent application. Based on the limited information contained in your letter dated May 12, 2003 to David Howard, we believe that it is unlikely that the claim scope outlined in that letter could be valid in light of the prior art. For example, I have attached a claim chart showing that the disclosure of U.S. Pat. No. 3,966,980 (the ''980 patent"), that was filed in 1969, that issued in 1976, and that expired in 1993, appears to anticipate or render obvious the claim scope outlined in your May 12, 2003 letter.

In addition to the '980 patent, we have found a substantial body of other prior art that is relevant to the patentability of the claim scope outlined in your May 12, 2003 letter, and our prior art search is continuing. This prior art shows that the method outlined in your May 12, 2003 letter was publicly known and used in the United States at least four years ago, and possibly much earlier. Please let me know if you would like further information regarding this material prior art.

Please direct any further correspondence in this matter to me. We look forward to your prompt response.

Very truly yours,



Rick L. Abegglen

Enclosures
cc: Mr. Phil Hinderaker (w/ encls.)

FELLERS, SNIDER, BLANKENSHIP, BAILEY & TIPPENS, P.C.

ATTORNEYS & COUNSELLORS AT LAW

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www.fellerssnider.com

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JOHN JOSEPH SNIDER (1928-1997)

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HARRY H. SELPH, II
WARREN F. BICKFORD IV
JOHN B. HEATLY
MICHAEL R. FORD
ERIC S. EISSENSTAT
STEVE STEPHENS
DONEEN DOUGLAS JONES
THOMAS J. ENIS*
BARBARA G. BOWERSOX
JOE C. LEWALLEN, JR.
DINO E. VIERA
GREG A. CASTRO
KEVIN R. DONELSON
ROY C. BREEDLOVE
MARK K. STONECIPHER
ANDREW L. WALDING
TODD A. NELSON*
DENNIS D. BROWN*
R. ALAN WEEKS*.*
R. DANIEL SCROGGINS*
TERRY L. WATT, PH.D.*
BRYAN N. B. KING
SCOTT R. ZINGERMAN*
BRENT M. JOHNSON
CHARLES C. CALLAWAY, JR.
WILLIAM H. WHITEHILL, JR.
RANDALL K. McCARTHY*
CURTIS M. LONG
STEVEN J. ADAMS
JAY P. WALTERS*.*
JAMES F. LEA, III*
JOHN D. RUSSELL*

SANFORD C. COATS
MARGARET A. BOMHOFF
FRED H. HOLMES*
KELLI M. MASTERS
BROOKS A. RICHARDSON*
N. JANINE WHEELER
TRAVIS A. FULKERSON
DANIEL P. DOOLEY*.*
RYAN T. LEONARD
R. TODD WADDELL
CHARLES R. WILLING

OF COUNSEL
JAP W. BLANKENSHIP
PAUL W. DUDMAN'
JACK E. PHILLIPS*
BILL D. McCARTHY*
TRACY A. POOLE
STEVEN W. BALLARD

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*ALSO ADMITTED IN MINNESOTA
*ALSO ADMITTED IN MISSOURI
*ALSO ADMITTED IN TEXAS
*ALSO ADMITTED IN VIRGINIA
*ALSO ADMITTED IN WASHINGTON, D.C.
*REGISTERED PATENT ATTORNEY

OKLAHOMA CITY ADDRESS
BANK ONE TOWER
100 NORTH BROADWAY, SUITE 1700
OKLAHOMA CITY, OKLAHOMA 73102-8820
TELEPHONE (405) 232-0621
FAX (405) 232-9659

WRITER'S DIRECT NUMBER

July 18, 2003

Rick L. Abegglen, Esq.
FOLEY & LARDNER
Verex Plaza
150 East Gilman Street
Madison, WI 53703-1481

Re: Unitherm Food Systems, Inc.
Your Ref. No. 038702-0115

Dear Mr. Abegglen:

As patent counsel for Unitherm Food Systems, Inc., I am writing in response to your July 1, 2003 letter to David Howard, president of Unitherm. Contrary to the allegations in your letter, we are confident that your client, ALKAR, fully understands that Unitherm has not asserted that it has yet obtained any patents pertaining to its pasteurization technology.

Although Unitherm is a small company, particularly when compared to ALKAR and others, Unitherm has a well-earned reputation for innovation and is justifiably excited about its breakthrough developments and discoveries for the pre and/or post pasteurization of food products. Some of Unitherm's new developments have been cited in recently issued FSIS Compliance Guidelines. It is with great pride, therefore, that Unitherm has announced and is marketing this technology to its customers, and will continue to do so.

In this context, and as entitled under the patent law, Unitherm has also announced to its customers that it has patent applications pending for these exciting innovations. These patent applications contain valuable proprietary information developed by Unitherm through months of

EXHIBIT 17

hard work and investment. As ALKAR is fully aware, Unitherm cannot hand this valuable information over to its competitors. Nor is ALKAR entitled to benefit from Unitherm's work. At the same time, however, Unitherm has been very responsive to specific customer questions concerning the subject matter and ongoing scope of the claims of its pending patent applications.

Moreover, Unitherm has demonstrated considerable willingness to accommodate any of its customers interested in licensing Unitherm pasteurization technologies which may eventually be patented. This, quite obviously, should be good news to ALKAR. In the event that Unitherm is successful in obtaining one or more patents, future licensees under such patents would be able to purchase the system(s) in question from ALKAR or from anyone else they choose.

Unitherm is committed to ethical conduct and fair dealing. Moreover, Unitherm has no desire to be involved in any disputes with its competitors. However, it is clear that Unitherm cannot allow itself to be intimidated and coerced into leaving the market, ceasing competition, or divulging its proprietary technology and information to its competitors. Therefore, if we have misunderstood your letter or if you can show that Unitherm has inadvertently done anything improper, we ask that you please bring this to our attention.

Sincerely,

FELLERS, SNIDER, BLANKENSHIP,
BAILEY & TIPPENS, P.C.

Dennis D. Brown

DDB:caw

215897.1

FELLERS, SNIDER, BLANKENSHIP, BAILEY & TIPPENS, P.C.

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*REGISTERED PATENT ATTORNEY

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TELEPHONE (405) 232-0621
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WRITER'S DIRECT NUMBER

August 11, 2003

Via Facsimile and Certified Mail No. 7002 3150 0004 4749 7526
Return Receipt Requested

Rick L. Abegglen, Esq.
FOLEY & LARDNER
P. O. Box 1497
Madison, WI 53701-1497

Re: Unitherm Food Systems, Inc.
Your Ref. No.: 038702-0115
Our Ref. No.: 03-519

Dear Mr. Abegglen:

We have reviewed your letter of July 30, 2003 but have found nothing of significance therein which was not already addressed in my letter to you dated July 18, 2003. To summarize, the essential points in this matter are that:

- Unitherm has not yet obtained any issued patents for its surface pasteurization technology
- Unitherm has never claimed to have yet obtained any patents for its surface pasteurization technology
- Unitherm is not aware of anyone in the industry that has used or is presently using a combined pre and post-surface pasteurization process of a type called for in Unitherm's pending patent applications

EXHIBIT18

- Unitherm has never threatened to take any legal action against anyone for any reason concerning Unitherm's proprietary surface pasteurization technology
- Unitherm has never "coerced" any customer of ALKAR.
- Unitherm has not disparaged ALKAR or its products
- Unitherm is under no obligation to disclose, and will not be bullied or coerced into disclosing, its proprietary surface pasteurization technology and information to its competitors

Your letter and the attachments thereto only serve to confirm these points.

We are also puzzled by your apparent contention that it is somehow improper for Unitherm to offer licenses for proprietary technologies which have not yet been patented. Such contention would clearly not be correct and would also conflict with ALKAR's own recent attempts to generate interest in the licensing of its purported proprietary technology for pasteurizing wieners.

Also, as to your demand that Unitherm immediately disclose the details of its proprietary surface pasteurization processes to ALKAR and everyone else, surely you are aware that the value of any proprietary, unpatented technology lies at least in significant part in the fact that the technology is not known by others. Thus, detailed information concerning proprietary technology is typically not disclosed to others unless (a) they have demonstrated a serious interest in licensing the technology and (b) appropriate confidentiality and non-circumvention agreements are in place.

Concerning your further accusations regarding Carolina Turkeys and ALKAR's other purported customers, it was Unitherm's understanding, based upon inquiries from Carolina Turkeys, that Carolina Turkeys desired to know whether any of the claims in Unitherm's pending patent applications, if patented, would cover a particular pre/post-pasteurization process having certain specific steps. Unitherm endeavored to respond to this request to the fullest extent possible without divulging its proprietary information. However, Carolina Turkeys has since informed Unitherm that Unitherm's understanding of the particular process of interest to Carolina Turkeys was incorrect and that Carolina Turkeys has no intention of ever using this process. Moreover, Unitherm is not aware that Carolina Turkeys, or anyone else, has ever practiced or has any present intention of practicing any pre/post-surface pasteurization processes relevant to Unitherm's pending patent applications. Nor has Unitherm ever stated that Carolina Turkeys, or anyone else, has used or intends to use any such process.

Finally, we have forwarded a copy of U.S. Patent No. 3,966,980 to the Patent Office. However, the proprietary surface pasteurization processes claimed in Unitherm's pending patent applications are quite different from known bag cooking, warming , and/or recooking procedures of the type disclosed in the '980 patent. Moreover, in view of the fact that the term of the '980 patent has expired, it is clear that the Method of Cooking and Storing Food in Flexible Bags disclosed therein is now in the public domain and can be freely used by ALKAR or anyone else.

It is Unitherm's sincere belief that all of ALKAR's accusations have been fully addressed and that this should be the end of the matter. Unfortunately, Unitherm has now had to respond to the same accusations twice, each response requiring considerable time and expense. Regrettably, we must therefore respectfully submit and inform you that any further correspondence repeating these or similar accusations would simply be mere harassment and will not be responded to.

Sincerely,

FELLERS, SNIDER, BLANKENSHIP,
BAILEY & TIPPENS, P.C.

Dennis D. Brown

DDB:caw
219408.1